Ab-16-001-0237

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

AUG 1 9 2016

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS

The Honorable Jason Chaffetz Chairman Committee on Oversight and Government Reform U.S. House of Representatives Washington, D.C. 20515

Dear Mr. Chairman:

I am writing today to supplement the U.S. Environmental Protection Agency's initial response of July 28, to your letter of July 14, 2016, in which you request certain information relating to the agency's regulatory analyses and approach to valuing reductions in mortality risk.

As indicated in our letter of July 28, and in a recent constructive conference call with your staff, the EPA is in the process of collecting the documents and communications you have requested. While this process continues, we are now able to produce a set of responsive documents that we referenced in our conversation with your staff.

The EPA recognizes the importance of the Committee's need to obtain information necessary to perform its legitimate oversight functions, and is committed to continuing to work with your staff on how best to accommodate the Committee's interests in the documents requested in your letter.

Please feel free to contact me if you have any questions, or your staff may contact Tom Dickerson in my office at dickerson.tom@epa.gov or (202) 564-3638.

Sincerely.

Nichole Distefano

Associate Administrator

Enclosures

cc: The Honorable Elijah E. Cummings

Ranking Member



U.S. Department of Transportation Office of the Secretary Of Transportation

1200 New Jersey Ave., S.E. Washington, DC 20590

June 17, 2015

MEMORANDUM TO:

SECRETARIAL OFFICERS

MODAL ADMINISTRATORS

From:

Kathryn Thomson

General Counsel, x69136

Carlos Monje

Assistant Secretary for Policy, x68152

Subject:

Guidance on Treatment of the Economic Value of a Statistical Life

(VSL) in U.S. Department of Transportation Analyses – 2015 Adjustment

Departmental guidance on valuing reduction of fatalities and injuries by regulations or investments has been published periodically by this office since 1993. We issued a thorough revision of our guidance in 2013 and indicated that we planned to issue annual updates to adjust for changes in prices and real incomes since then.

Our 2013 revision indicated a VSL of \$9.1 million in current dollars for analyses using a base year of 2012. Using the 2013 value as a baseline, and taking into account both changes in prices and changes in real incomes, we now find that these changes over the past year imply an increased VSL of \$9.4 million for analyses prepared in 2015. Last year the VSL was \$9.2 million. The procedure for adjusting VSL for changes in prices and real incomes is described on pages 6-7 of the guidance.

This guidance also includes a table of the relative values of preventing injuries of varied severity, unchanged since the 2013 guidance. We also prescribe a sensitivity analysis of the effects of using alternative VSL values. Instead of treating alternative values in terms of a probability distribution, analysts should apply only a test of low and high alternative values of \$5.2 million and \$13.0 million.

This guidance and other relevant documents will be posted on the Reports page of the Office of Transportation Policy website, http://www.dot.gov/policy, and on the General Counsel's regulatory information website, http://www.dot.gov/regulations. Questions should be addressed to Tony Homan, (202) 366-5406 or anthony.homan@dot.gov.

cc: Regulations officers and liaison officers

Revised Departmental Guidance 2014:

Treatment of the Value of Preventing Fatalities and Injuries in Preparing Economic Analyses

On the basis of the best available evidence, this guidance identifies \$9.4 million as the value of a statistical life to be used for Department of Transportation analyses assessing the benefits of preventing fatalities and using a base year of 2013. It also establishes policies for projecting future values and for assigning comparable values to prevention of injuries.

Background

Prevention of injury, illness, and loss of life is a significant factor in many private economic decisions, including job choices and consumer product purchases. When government makes direct investments or controls external market impacts by regulation, it also pursues these benefits, often while also imposing costs on society. The Office of the Secretary of Transportation and other DOT administrations are required by Executive Order 13563, Executive Order 12866, Executive Order 12893, OMB Circular A-4, and DOT Order 2100.5 to evaluate in monetary terms the costs and benefits of their regulations, investments, and administrative actions, in order to demonstrate the faithful execution of their responsibilities to the public. Since 1993, the Office of the Secretary of Transportation has periodically reviewed the published research on the value of safety and updated guidance for all administrations. Our previous guidance, issued on February 28, 2013, stated that we planned to update our guidance annually to adjust for changes in prices and real incomes. This guidance updates our values based on 2013 prices and real incomes.

The benefit of preventing a fatality is measured by what is conventionally called the Value of a Statistical Life (VSL), defined as the additional cost that individuals would be willing to bear for improvements in safety (that is, reductions in risks) that, in the aggregate, reduce the expected number of fatalities by one. This conventional terminology has often provoked misunderstanding on the part of both the public and decision-makers. What is involved is not the valuation of life as such, but the valuation of reductions in risks. While new terms have been proposed to avoid misunderstanding, we will maintain the common usage of the research literature and OMB Circular A-4 in referring to VSL.

Most regulatory actions involve the reduction of risks of low probability (as in, for example, a one-in-10,000 annual chance of dying in an automobile crash). For these low-probability risks, we shall assume that the willingness to pay to avoid the risk of a fatal injury increases proportionately with growing risk. That is, when an individual is willing to pay \$1,000 to reduce the annual risk of death by one in 10,000, she is said to have a VSL of \$10 million. The assumption of a linear relationship between risk and willingness to pay therefore implies that she would be willing to pay \$2,000 to reduce risk by two in 10,000 or \$5,000 to reduce risk by five in 10,000. The assumption of a linear relationship between risk and willingness to pay (WTP) breaks down when the annual WTP becomes a substantial portion of annual income, so the assumption of a constant VSL is not appropriate for substantially larger risks.

When first applied to benefit-cost analysis in the 1960s and 1970s, the value of saving a life was measured by the potential victim's expected earnings, measuring the additional product society might have lost. These lost earnings were widely believed to understate the real costs of loss of life, because the value that we place on the continued life of our family and friends is not based entirely, or even principally, on their earning capacity. In recent decades, studies based on estimates of individuals' willingness to pay for improved safety have become widespread, and offer a way of measuring the value of reduced risk in a more comprehensive way. These estimates of the individual's value of safety are then treated as the ratio of the individual marginal utility of safety to the marginal utility of wealth. These estimates of the individual values of changes in safety can then be aggregated to produce estimates of social benefits of changes in safety, which can then be compared with the costs of these changes.

Studies estimating the willingness to pay for safety fall into two categories. Some analyze subjects' responses in real markets, and are referred to as revealed preference (RP) studies, while others analyze subjects' responses in hypothetical markets, and are described as stated preference (SP) studies. Revealed preference studies in turn can be divided into studies based on consumer purchase decisions and studies based on employment decisions (usually referred to as hedonic wage studies). Even in revealed preference studies, safety is not purchased directly, so the value that consumers place upon it cannot be measured directly. Instead, the value of safety can be inferred from market decisions that people make in which safety is one factor in their decisions. In the case of consumer purchase decisions, since goods and services usually display multiple attributes, and are purchased for a variety of reasons, there is no guarantee that safety will be the conclusive factor in any purchasing decision (even products like bicycle helmets, which are purchased primarily for safety, also vary in style, comfort, and durability). Similarly, in employment decisions, safety is one of many considerations in the decision of which job offer to accept. Statistical techniques must therefore be used to identify the relative influence of price (or wage), safety, and other qualitative characteristics of the product or job on the consumer's or worker's decision on which product to buy or which job to accept.

An additional complication in RP studies is that, even if the real risks confronted by individuals can be estimated accurately by the analyst, the consumer or employee may not estimate these risks accurately. It is possible for individuals, through lack of relevant information or limited ability to analyze risks, to assign an excessively low or high probability to fatal risks. Alternatively, detailed familiarity with the hazards they face and their own skills may allow individuals to form more accurate estimates of risk at, for example, a particular job-site than those derived by researchers, which inevitably are based on more aggregate data.

In the SP approach, market alternatives incorporating hypothetical risks are presented to test subjects, who respond with what they believe would be their choices. Answers to hypothetical questions may provide helpful information, but they remain hypothetical. Although great pains are usually taken to communicate probabilities and measure the subjects' understanding, there is no assurance that individuals' predictions of their own behavior would be observed in practice. Against this weakness, the SP method can evaluate many more alternatives than those for which market data are available, and it can guarantee that risks are described objectively to subjects. With indefinitely large potential variations in cost and risk and no uncontrolled variation in any

other dimension, some of the objections to RP models are obviated. Despite procedural safeguards, however, SP studies have not proven consistently successful in estimating measures of WTP that increase proportionally with greater risks.

RP studies involving decisions to buy and/or use various consumer products have focused on decisions such as buying cars with better safety equipment, wearing seat belts or helmets, or buying and installing smoke detectors. These studies often lack a continuum of price-risk opportunities, so that the price paid for a safety feature (such as a bicycle helmet) does not necessarily represent the value that the consumer places on the improvement in safety that the helmet provides. In the case of decisions to use a product (like a seatbelt) rather than to buy the product, the "price" paid by the consumer must be inferred from the amount of time and degree of inconvenience involved in using the product, rather than the directly observable price of buying the product. The necessity of making these inferences introduces possible sources of error. Studies of purchases of automobiles probably are less subject to these problems than studies of other consumer decisions, because the price of the safety equipment is directly observable, and there are usually a variety of more or less expensive safety features that provide more of a range of price-risk trade-offs for consumers to make.

While there are many examples of SP studies and RP studies involving consumer product purchases, the most widely cited body of research comprises hedonic wage studies, which estimate the wage differential that employers must pay workers to accept riskier jobs, taking other factors into account. Besides the problem of identifying and quantifying these factors, researchers must have a reliable source of data on fatality and injury risks and also assume that workers' psychological risk assessment conforms to the objective data. The accuracy of hedonic wage studies has improved over the last decade with the availability of more complete data from the Bureau of Labor Statistics' (BLS) Census of Fatal Occupational Injuries (CFOI), supported by advances in econometric modeling, including the use of panel data from the Panel Study of Income Dynamics (PSID). The CFOI data are, first of all, a complete census of occupational fatalities, rather than a sample, so they allow more robust statistical estimation. Second, they classify occupational fatalities by both industry and occupation, allowing variations in fatalities across both dimensions to be compared with corresponding variations in wage rates. Some of the new studies use panel data to analyze the behavior of workers who switch from one job to another, where the analysis can safely assume that any trade-off between wage levels and risk reflects the preferences of a single individual, and not differences in preferences among individuals.

VSL estimates are based on studies of groups of individuals that are covered by the study, but those VSL estimates are then applied to other groups of individuals who were not the subjects of the original studies. This process is called benefit transfer. One issue that has arisen in studies of VSL is whether this benefit transfer process should take place broadly over the general population of people that are affected by a rulemaking, or whether VSL should be estimated for particular subgroups, such as workers in particular industries, and people of particular ages, races, and genders. Advances in data and econometric techniques have allowed specialized estimates of VSL for these population subgroups. Safety regulations issued by the Department of Transportation typically affect a broad cross-section of people, rather than more

narrowly defined subgroups. Partly because of that, and partly for policy reasons, we do not consider variations in VSL among different population groups (except to take into account the effect on VSL of rising real income over time).

Principles and policies of DOT guidance

This guidance for the conduct of Department of Transportation analyses is a synthesis of empirical estimates, practical adaptations, and social policies. We continue to explore new empirical literature as it appears and to give further consideration to the policy resolutions embodied in this guidance. Although our approach is unchanged from previous guidance, the numbers and their sources are new, consistent with OMB guidance in Circular A-4 and other sources, and with the use of the best available evidence. The methods we adopt are:

- 1. Prevention of an expected fatality is assigned a single, nationwide value in each year, regardless of the age, income, or other distinct characteristics of the affected population, the mode of travel, or the nature of the risk. When Departmental actions have distinct impacts on infants, disabled passengers, or the elderly, no adjustment to VSL should be made, but analysts should call the attention of decision-makers to the special character of the beneficiaries.
- 2. In preparing this guidance, we have adjusted the VSL from the year of the source data to the year before the guidance is issued, based on two factors: growth in median real income and monetary inflation, both measured to the last full year before the date of the guidance.
- 3. The value to be used by all DOT administrations will be published annually by the Office of the Secretary of Transportation.
- 4. Analysts should project VSL from the base year to each future year based on expected growth in real income, according to the formula prescribed on page 8 of this guidance. Analysts should not project future changes in VSL based on expected changes in price levels.
- 5. Alternative high and low benefit estimates should be prepared, using a range of VSLs prescribed on pages 10-11 of this guidance

In Circular A-4 (2003), the Office of Management and Budget endorsed VSL values between \$1 million and \$10 million, drawing on two recently completed VSL meta-analyses. In 2013 dollars, these values would be between \$1.25 million and \$12.5 million. The basis for our 2008 guidance comprised five studies, four of which were meta-analyses that synthesized many primary studies, identifying their sources of variation and estimating the most likely common

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¹ Viscusi, W. K. and J.E. Aldy (2003). "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World." *Journal of Risk and Uncertainty*, 27(1): 5-76; and Mrozek, J.R. and L. O. Taylor (2002). "What Determines the Value of a Life? A Meta-Analysis." *Journal of Policy Analysis and Management*. 21(2).

parameters. These studies were written by Ted R. Miller;² Ikuho Kochi, Bryan Hubbell, and Randall Kramer;³ W. Kip Viscusi;⁴ Janusz R. Mrozek and Laura O. Taylor;⁵ and W. Kip Viscusi and Joseph Aldy.⁶ They narrowed VSL estimates to the \$2 million to \$7 million range in dollar values of the original data, between 1995 and 2000 (about \$3 million to \$9 million at current prices). Miller and Viscusi and Aldy also estimated income elasticities for VSL (the percent increase in VSL per one percent increase in income). Miller's estimates were close to 1.0, while Viscusi and Aldy estimated the elasticity to be between 0.5 and 0.6. DOT used the Viscusi and Aldy elasticity estimate (averaged to 0.55), along with the Wages and Salaries component of the Employer Cost for Employee Compensation, as well as price levels represented by the Consumer Price Index, to project these estimates to a 2007 VSL estimate of \$5.8 million.

Since these studies were published, the credibility of these meta-analyses has been qualified by recognition of weaknesses in the data used by the earlier primary studies whose results are synthesized in the meta-analyses. We now believe that the most recent primary research, using improved data (particularly the CFOI data discussed above) and specifications, provides more reliable results. This conclusion is based in part on the advice of a panel of expert economists that we convened to advise us on this issue. The panel consisted of Maureen Cropper (University of Maryland), Alan Krupnick (Resources for the Future), Al McGartland (Environmental Protection Agency), Lisa Robinson (independent consultant), and W. Kip Viscusi (Vanderbilt University). The Panel unanimously concluded that we should base our guidance only on hedonic wage studies completed within the past 10 years that made use of the CFOI database and used appropriate econometric techniques.

A White Paper prepared for the U.S. Environmental Protection Agency (EPA) in 2010 identified eight hedonic wage studies using the CFOI data; we also identified seven additional studies, including five published since the EPA White Paper was issued (see Table 1). Some of these studies focus on estimating VSL values for narrowly defined economic, demographic, or occupational categories, or use inappropriate econometric techniques, resulting in implausibly high VSL estimates. We therefore focused on nine studies that we think are useful for informing an appropriate estimate of VSL. There is broad agreement among researchers that these newer hedonic wage studies provide an improved basis for policy-making.

²Miller, T. R. (2000). "Variations between Countries in Values of Statistical Life." *Journal of Transport Economics and Policy*. 34(2): 169-188. http://www.bath.ac.uk/e-journals/jtep/pdf/Volume_34_Part_2_169-188.pdf ³Kochi, l., B. Hubbell, and R. Kramer (2006). "An Empirical Bayes Approach to Combining and Comparing Estimates of the Value of a Statistical Life for Environmental Policy Analysis." *Environmental and Resource Economics*. 34(3): 385-406.

⁴Viscusi, W. K. (2004). "The Value of Life: Estimates with Risks by Occupation and Industry." *Economic Inquiry*. 42(1): 29-48.

⁵ Mrozek, J. R., and L. O. Taylor (2002). "What Determines the Value of Life? A Meta-Analysis." *Journal of Policy Analysis and Management*. 21(2).

⁶ Viscusi, W. K. and J. E. Aldy (2003). "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World." *Journal of Risk and Uncertainty*. 27(1): 5-76.

⁷ U.S. Environmental Protection Agency (2010), Valuing Mortality Risk Reductions for Environmental Policy: A White Paper (Review Draft). Prepared by the National Center for Environmental Economics for consultation with the Science Advisory Board – Environmental Economics Advisory Committee.

⁸A current survey of theoretical and empirical research on VSL may be found in: Cropper, M., J.K. Hammitt, and

The 15 hedonic wage studies we have identified that make use of the CFOI database to estimate VSL are listed in Table 1. Several of these studies focus on estimating how VSL varies for different categories of people, such as males and females, older workers and younger workers, to blacks and whites, immigrants and non-immigrants, and smokers and non-smokers, as well as for different types of fatality risks. Some of these studies do not estimate an overall ("full-sample") VSL, instead estimating VSL values only for specific categories of people. Some of the studies, as the authors themselves sometimes acknowledge, arrive at implausibly high values of VSL, because of econometric specifications which appear to bias the results, or because of a focus on a narrowly-defined occupational group. Moreover, these papers generally offer multiple model specifications, and it is often not clear (even to the authors) which specification most accurately represents the actual VSL. We have generally chosen the specification that the author seems to believe is best. In cases where the author does not express a clear preference, we have had to average estimates based on alternative models within the paper to get a representative estimate for the paper as a whole.

Table 1: VSL Studies Using CFOI Database

(VSLs in millions of dollars)

	<u>Study</u>	Year of	VSL in Study-	VSL in	Comments
		<u>Study</u>	Year \$	<u>2012\$</u>	
		\$			· j
1	Viscusi (2003) *	1997	\$14.185M	\$21.65M	Implausibly high;
5 g					industry-only risk measure
2.	Leeth and Ruser (2003) *	2002	\$7.04M 🦠	\$8,90M	Occupation-only risk
3 A 3 A					measure
- 3.	Viscusi (2004)	1997	\$4.7M	\$7.17M	Industry/occupation risk

L.A. Robinson (2011). "Valuing Mortality Risk Reductions: Progress and Challenges." Annual Review of Resource Economics. 3: 313-336.

http://www.annualreviews.org/doi/abs/10.1146/annurev.resource.012809.103949

⁹ Leeth, J.D. and J. Ruser (2003). "Compensating Wage Differentials for Fatal and Nonfatal Injury Risks by Gender and Race." Journal of Risk and Uncertainty, 27(3): 257-277.

¹⁰ Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2006). "Life-Cycle Consumption and the Age-Adjusted Value of Life." Contributions to Economic Analysis and Policy. 5(1): 1-34; Viscusi, W.K. and J.E. Aldy (2007). "Labor Market Estimates of the Senior Discount for the Value of Statistical Life." Journal of Environmental Economics and Management. 53: 377-392; Aldy, J.E. and W.K. Viscusi (2008). "Adjusting the Value of a Statistical Life for Age and Cohort Effects." Review of Economics and Statistics. 90(3): 573-581; and Evans, M.F. and G. Schaur (2010). "A Quantile Estimation Approach to Identify Income and Age Variation in the Value of a Statistical Life." Journal of Environmental Economics and Management. 59: 260-270.

¹¹ Viscusi, W.K. (2003). "Racial Differences in Labor Market Values of a Statistical Life." *Journal of Risk and Uncertainty*. 27(3): 239-256, and Leeth, J.D. and J. Ruser (2003), op. cit.

¹² Hersch, J. and W.K. Viscusi (2010). "Immigrant Status and the Value of Statistical Life." *Journal of Human Resources*. 45(3): 749-771.

¹³ Viscusi, W.K. and J. Hersch (2008). "The Mortality Cost to Smokers." Journal of Health Economics. 27: 943-

¹⁴ Scotton, C.R. and L.O. Taylor. "Valuing Risk Reductions: Incorporating Risk Heterogeneity into a Revealed Preference Framework." *Resource and Energy Economics*. 33 and Kochi, I and L.O. Taylor (2011). "Risk Heterogeneity and the Value of Reducing Fatal Risks: Further Market-Based Evidence." *Journal of Benefit-Cost Analysis*. 2(3): 381-397.

					measure
4.	Kniesner and Viscusi (2005)	1997	\$4.74M	\$7.23M	Industry/occupation risk measure
. 5.	Kniesner et al. (2006) *	1997	\$23.70M	\$36.17M	Implausibly high; industry/occupation risk measure
6.	Viscusi and Aldy (2007)	2000			Industry-only risk measure; no full-sample VSL estimate
7.	Aldy and Viscusi (2008)	2000		1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Industry-only risk measure, no full-sample VSL estimate
8.	Evans and Smith (2008)	2000	\$9.6M	\$12.84M	Industry-only risk measure
9.	Viscusi and Hersch (2008)	2000	\$7.37M	\$9.86M	Industry-only risk measure
10.	Evans and Schaur (2010)	1998	\$6.7M	\$9.85M	Industry-only risk measure
11.	Hersch and Viscusi (2010)	2003	\$6.8M	\$8.43M	Industry/occupation risk measure
12.	Kniesner et al. (2010)	2001	\$7.55M	\$9.76M	Industry/occupation risk measure
13.	Kochi and Taylor (2011)*	2004			VSL estimated only for occu-pational drivers
14.	Scotton and Taylor (2011)	1997	\$5.27M	\$8.04M	Industry/occupation risk measure; VSL is mean of estimates from three preferred specifications
15.	Kniesner et al. (2012)	2001	\$4M - \$10M	\$5.17M - \$12.93M	Industry/occupation risk measure; mean VSL estimate is \$9.05M

^{*} Studies shown in grayed-out rows were not used in determining the VSL Guidance value.

We found that nine of these studies provided usable estimates of VSL for a broad cross-section of the population. We excluded Viscusi (2003) and Kniesner et al. (2006) on the grounds that their estimates of VSL were implausibly high (Viscusi acknowledges that the estimated VSLs in his study are very high). We excluded Leeth and Ruser (2003) because it used only variations in occupation for estimating variation in risk (the occupational classifications are generally regarded as less accurate than the industry classifications). We excluded Viscusi and Aldy (2007) and Aldy and Viscusi (2008) because they did not estimate overall "full-sample" VSLs

¹⁵ In addition to Viscusi (2004) [cited in footnote 4], Viscusi and Hersch (2008) [cited in footnote 13], Evans and Schaur (2010) [cited in footnote 10], Hersch and Viscusi (2010) [cited in footnote 12], and Scotton and Taylor (2011) [cited in footnote 14], these include Kniesner, T.J. and W.K. Viscusi (2005). "Value of a Statistical Life: Relative Position vs. Relative Age." AEA Papers and Proceedings. 95(2): 142-146; Evans, M.F. and V.K. Smith (2008). "Complementarity and the Measurement of Individual Risk Tradeoffs: Accounting for Quantity and Quality of Life Effects." National Bureau of Economic Research Working Paper 13722; Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2010). "Policy Relevant Heterogeneity in the Value of Statistical Life: New Evidence from Panel Data Quantile Regressions." Journal of Risk and Uncertainty. 40: 15-31; and Kniesner, T.J., W.K. Viscusi, C. Woock, and J.P. Ziliak (2012). "The Value of a Statistical; Life: Evidence from Panel Data." Review of Economics and Statistics. 94(1): 74-87.

(they focused instead on estimating VSLs for various subgroups). We excluded Kochi and Taylor (2011) because it estimated VSL only for a narrow occupational group (occupational drivers). For Scotton and Taylor (2011) and Kniesner *et al.* (2012) we calculated average values for VSL from what appeared to be the preferred model specifications. For our 2013 guidance, we adopted the average of the VSLs estimated in the remaining nine studies, updated to 2012 dollars (based both on changes in the price level and changes in real incomes from the year for which the VSL was originally estimated). This average was \$9.14 million, which we rounded to \$9.1 million for purposes of that guidance.

For any one study, updating to 2012 was essentially multiplying the base year VSL of that study by the ratio of 2012 CPI to the study's base year CPI and by the ratio of 2012 Real Incomes to the study's base year Real Incomes. The following equation shows the calculation:

2012 VSL = Base Year VSL * (2012 CPI/Base Year CPI) * (2012 Real Incomes/Base Year Real Incomes)

For example, in the case of the 2005 Kniesner and Viscusi study, the VSL estimate is \$4.74 million in 1997 dollars. To adjust that 1997 estimate to 2012 dollars, we use the ratio of 2012 CPI to 1997 CPI and the ratio of 2012 real dollars to 1997 real dollars. The resulting estimate in 2012 dollars is \$7.23 million:

\$7.23 million (\$2012) = \$4.74 million * (229.594/160.5) * (335/314)

Our VSL guidance will be updated each year to take into account both the increase in the price level and the increase in real incomes. The procedure for updating the overall VSL value is the same as that for updating values for individual VSL studies shown above. The VSL literature is generally in agreement that VSL increases with real incomes, but the exact rate at which it does so is subject to some debate. In our 2011 guidance, we cited research by Viscusi and Aldy (2003) that estimated the elasticity of VSL with respect to increases in real income as being between 0.5 and 0.6 (i.e., a one-percent increase in real income results in an increase in VSL of 0.5 to 0.6 percent). We accordingly increased VSL by 0.55 percent for every one-percent increase in real income. More recent research by Kniesner, Viscusi, and Ziliak (2010) has derived more refined income elasticity estimates ranging from 2.24 at low incomes to 1.23 at high incomes, with an overall figure of 1.44. An alternative specification yielded an overall elasticity of 1.32. Similarly, Costa and Kahn (2004) estimated the income-elasticity of VSL to be between 1.5 and 1.6. These empirical results are consistent with theoretical arguments suggesting that the income-elasticity of VSL should be greater than 1.0.

¹⁶ Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2010). "Policy Relevant Heterogeneity in the Value of Statistical Life: New Evidence from Panel Data Quantile Regressions." *Journal of Risk and Uncertainty*. 40(1):15–31. ¹⁷ Costa, D.L. and M.E. Kahn (2004). "Changes in the Value of Life, 1940-1980." *Journal of Risk and Uncertainty*. 29(2): 159-180.

¹⁸ Eeckhoudt, L.R. and J.K. Hammitt (2001). "Background Risks and the Value of a Statistical Life." *Journal of Risk and Uncertainty*. 23(3): 261-279; Kaplow, L. (2005). "The Value of a Statistical Life and the Coefficient of Relative Risk Aversion." *Journal of Risk and Uncertainty*, 31(1); Murphy, K.M. and R.H. Topel (2006). "The Value of Health and Longevity." *Journal of Political Economy*. 114(5): 871-904; and Hammitt,

In view of the large increase in the income elasticity of VSL that would be suggested by these empirical results, and because the literature seems somewhat unsettled, we decided in our 2013 guidance to increase our suggested income-elasticity figure only to 1.0. While this figure is lower than the elasticity estimates of Kniesner *et al.* and Costa and Kahn, it is higher than that of Viscusi and Aldy, the basis for our previous guidance. It is difficult to state with confidence whether a cross-sectional income elasticity (such as those estimated in these empirical analyses), representing the difference in sensitivity to fatality risks between low-income and high-income workers in a given population, corresponds to a longitudinal elasticity, representing the way in which VSL is affected by growth in income over time for an overall population. Consequently, we adopt this more moderate figure, pending more comprehensive documentation.

The index we use to measure real income growth as it affects VSL is the Median Usual Weekly Earnings (MUWE), in constant (1982-84) dollars, derived by BLS from the Current Population Survey (Series LEU0252881600 – not seasonally adjusted). This series is more appropriate than the Wages and Salaries component of the Employment Cost Index (ECI), which we used previously, because the ECI applies fixed weights to employment categories, while the weekly earnings series uses a median employment cost for wage and salary workers over the age of 16. A median value is preferred because it should better reflect the factors influencing a typical traveler affected by DOT actions (very high incomes would cause an increase in the mean, but not affect the median). In contrast to a median, an average value over all income levels might be unduly sensitive to factors that are less prevalent among actual travelers. Similarly, we do not take into account changes in non-wage income, on the grounds that this non-wage income is not likely to be significant for the average person affected by our rules. The MUWE has been virtually unchanged for the past decade, so this has very little effect on the VSL adjustment over the past ten years. However, it is likely to be more significant in the future.

We have chosen the Consumer Price Index for All Urban Consumers Current Series (CPI-U) as a price index that similarly is representative of changes in the value of money that would be considered by a typical worker making decisions corresponding to his income level. This index grew from 2002 to 2012 by 27.62 percent, raising estimates of VSL in 2002 dollars by over 27 percent over ten years.

When conducting sensitivity analyses using alternative VSL values (see page 12), analysts should use those alternative VSL values in place of the \$9.4 million value used here. For analysts using base years prior to 2013, the VSL for 2012 (adjusted for changes in real income and prices) is \$9.1 million. For 2011 this value was \$9.0 million in 2011 dollars.

Value of Preventing Injuries

Nonfatal injuries are far more common than fatalities and vary widely in severity, as well as probability. In principle, the resulting losses in quality of life, including both pain and suffering

and reduced income, should be estimated by potential victims' WTP for personal safety. While estimates of WTP to avoid injury are available, often as part of a broader analysis of factors influencing VSL, these estimates are generally only available for an average injury resulting in a lost workday, and not for a range of injuries varying in severity. Because detailed WTP estimates covering the entire range of potential disabilities are unobtainable, we use an alternative standardized method to interpolate values of expected outcomes, scaled in proportion to VSL. Each type of accidental injury is rated (in terms of severity and duration) on a scale of quality-adjusted life years (QALYs), in comparison with the alternative of perfect health. These scores are grouped, according to the Abbreviated Injury Scale (AIS), yielding coefficients that can be applied to VSL to assign each injury class a value corresponding to a fraction of a fatality.

In our 2011 guidance, the values of preventing injuries were updated by new estimates from a study by Spicer and Miller. ¹⁹ The measure adopted was the quality-adjusted percentage of remaining life lost for median utility weights, based on QALY research considered "best," as presented in Table 9 of the cited study. The rate at which disability is discounted over a victim's lifespan causes these percentages to vary slightly, and the study shows estimates for 0, 3, 4, 7, and 10 percent discount rates. These differences are minor in comparison with other sources of variation and uncertainty, which we recognize by sensitivity analysis. Since OMB recommends the use of alternative discount rates of 3 and 7 percent, we present the scale corresponding to an intermediate rate of 4 percent for use in all analyses. The fractions shown should be multiplied by the current VSL to obtain the values of preventing injuries of the types affected by the government action being analyzed.

Table 2: Relative Disutility Factors by Injury Severity Level (AIS)

For Use with 3% or 7% Discount Rate

AlS Level	Severity	Fraction of VSL
AIS 1	Minor	0.003
AIS 2	Moderate	0.047
AIS 3	Serious	0.105
AIS 4	Severe	0.266
AIS 5	Critical	0.593
AIS 6	Unsurvivable	1.000

For example, if the analyst were seeking to estimate the value of a "serious" injury (AIS 3), he or she would multiply the Fraction of VSL for a serious injury (0.105) by the VSL (\$9.4)

¹⁹ Rebecca S. Spicer and Ted R. Miller. "Final Report to the National Highway Traffic Safety Administration: Uncertainty Analysis of Quality Adjusted Life Years Lost." Pacific Institute for Research and Evaluation. February 5, 2010. http://ostpxweb.dot.gov/policy/reports/QALY Injury Revision_PDF Final Report 02-05-10.pdf.

million) to calculate the value of the serious injury (\$987,000). Values for injuries in the future would be calculated by multiplying these Fractions of VSL by the future values of VSL (calculated using the formula on page 8).

These factors have two direct applications in analyses. The first application is as a basis for establishing the value of preventing nonfatal injuries in benefit-cost analysis. The total value of preventing injuries and fatalities can be combined with the value of other economic benefits not measured by VSLs, and then compared to costs to determine either a benefit/cost ratio or an estimate of net benefits.

The second application stems from the requirement in OMB Circular A-4 that evaluations of major regulations for which safety is the primary outcome include cost-effectiveness analysis, in which the cost of a government action is compared with a non-monetary measure of benefit. The values in the above table may be used to translate nonfatal injuries into fatality equivalents which, when added to fatalities, can be divided into costs to determine the cost per equivalent fatality. This ratio may also be seen as a "break-even" VSL, the value that would have to be assumed if benefits of a proposed action were to equal its costs. It would illustrate whether the costs of the action can be justified by a VSL that is well within the accepted range or, instead, would require a VSL approaching the upper limit of plausibility. Because the values assigned to prevention of injuries and fatalities are derived in part by using different methodologies, it is useful to understand their relative importance in drawing conclusions. Consequently, in analyses where benefits from reducing both injuries and fatalities are present, the estimated values of injuries and fatalities prevented should be stated separately, as well as in the aggregate.

While these injury disutility factors have not been revised in this update of our VSL guidance, the peer review process for this guidance raised the question as to whether their accuracy could be further improved. We therefore believe that a more thorough review of the value of preventing injuries is warranted. While the results of that review are not incorporated in this guidance, we plan to incorporate the results of that review in future guidance as soon as it is completed.

Recognizing Uncertainty

Regulatory and investment decisions must be made by officials informed of the limitations of their information. The values we adopt here do not establish a threshold dividing justifiable from unjustifiable actions; they only suggest a region where officials making these decisions can have relatively greater or lesser confidence that their decisions will generate positive net benefits. To convey the sensitivity of this confidence to changes in assumptions, OMB Circular A-4 and Departmental policy require analysts to prepare estimates using alternative values. We have previously encouraged the use of probabilistic methods such as Monte Carlo analysis to synthesize the many uncertain quantities determining net benefits.

While the individual estimates of VSL reported in the studies cited above are often accompanied by estimates of confidence intervals, we do not, at this time, have any reliable method for estimating the overall probability distribution of the average VSL that we have calculated from these various studies. Consequently, alternative VSL values can only illustrate the conclusions that would result if the true VSL actually equaled the higher or lower alternative

values. Analysts should not imply a known probability that the true VSL would exceed or fall short of either the primary VSL figure or the alternative values used for sensitivity analysis. Kniesner et al. (2012) suggest that a reasonable range of values for VSL is between \$4 million and \$10 million (in 2001 dollars), or \$5.2 million to \$13.0 million in 2013 dollars. This range of values includes all the estimates from the eight other studies on which this guidance is based. For illustrative purposes, analysts should calculate high and low alternative estimates of the values of fatalities and injuries by using alternative VSLs of \$5.2 million and \$13.0 million, with appropriate adjustments for future VSL values and for values of injuries calculated using the VSL.

Because the relative costs and benefits of different provisions of a rule can vary greatly, it is important to disaggregate the provisions of a rule, displaying the expected costs and benefits of each provision, together with estimates of costs and benefits of reasonable alternatives to each provision.

This guidance and other relevant documents will be posted on the Reports page of the Office of Transportation Policy website, http://www.dot.gov/policy. Questions should be addressed to Tony Homan, (202) 366-5406, or anthony.homan@dot.gov.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

September 24, 2009

EPA-SAB-09-018

The Honorable Lisa P. Jackson Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

> Subject: Science Advisory Board (SAB) Advisory on EPA's draft Guidelines for Preparing Economic Analyses (2008)

Dear Administrator Jackson:

EPA's National Center for Environmental Economics requested that the SAB review EPA's draft *Guidelines for Preparing Economic Analyses* (2008). The *Guidelines*, originally issued in 2000 and recently updated, represent Agency policy on the preparation of economic analysis required by legislative and administrative mandates and are intended to provide technical guidance to analysts on the economic analysis of environmental policy. The SAB Environmental Economics Advisory was impressed with many facets of the updated *Guidelines*. We applaud EPA for a number of carefully revised chapters and substantively improved coverage of many topics. In the enclosed report, we provide responses to EPA's charge questions and recommendations for additional improvements. In this letter, we provide highlights of our overarching comments.

The current draft of the *Guidelines* could be improved by clearly identifying EPA's role and discretion in setting environmental policy. Specifically, policy options are described in the *Guidelines* in a manner that could allow the reader to infer that EPA has the discretion to choose from a variety of policy instruments (e.g., regulations or taxes) to achieve environmental targets. In reality, of course, only the legislative branch has the power to tax, subsidize or assign liability, and both the Clean Water Act and the Clean Air Act very clearly specify what kinds of regulations EPA may promulgate. The *Guidelines* should make clear that while economic analysis can identify superior policy options, EPA's legal authority defines its menu of choices. This might be done quite effectively by using examples from legislation to make the limitations concrete.

In addition to clarifying EPA's role in policy, the *Guidelines* should be grounded in the realities of information and political constraints, as well as market distortions,

either market induced or created by government interventions --- so named "second best" conditions. For example, the theory section focuses on first-best policy choices but this framework is nearly irrelevant to contemporary water pollution problems. The section on subsidies does not acknowledge that many subsidies in agriculture, car manufacturing, oil and gas, etc. are not designed to correct externalities but may in fact worsen them. Examples, such as the perverse incentives created by federal subsidies for corn-derived ethanol, are needed to illustrate these issues.

The Guidelines provide scant coverage of the long-standing issue in benefit-cost analysis of valuing the benefits of protecting ecological systems and services. Monetizing ecosystem services remains an area of significant challenge. The Guidelines should discuss situations where "non-monetized" benefits are expected to be a significant portion of the regulatory outcome including advice for practitioners in this case and noting that adherence to formal dollar-based benefit-cost analysis can lead to incorrect efficiency signals. We note that the recent SAB report on Valuing the Protection of Ecological Systems and Services (2009) provides useful insights on this topic.

The literature cited in the *Guidelines* needs to be updated. In its coverage of economic valuation methods for benefits analysis, the *Guidelines* did not incorporate numerous new studies using revealed preference methods, stated preference, approaches combining the two, and experiments in the lab and field. Other areas in which the literature needs updating include mortality benefits valuation, empirical work on the limited effectiveness of voluntary approaches (without financial incentives) and water quality trading.

The Guidelines could also be strengthened with case studies. For example, the Guidelines identify the basic steps involved in "benefits transfer" (using values of environmental quality estimates for one location to value changes at another), but readers would benefit substantively from a concrete real world example. The Guidelines enumerate a step-by-step approach for economic impact analysis but again, readers would benefit from a specific example from EPA's own experience. The Guidelines' discussion of environmental equity impacts would be greatly enriched with a case study.

Finally, the *Guidelines* are focused on economic analysis needed for "traditional" environmental problems, e.g., chemical releases from point sources to air and water. Given the emergence of climate change as the preeminent environmental threat, EPA will need more complex, interdisciplinary analysis to address greenhouse gas mitigation including information from the bio-physical sciences, economics and atmospheric sciences. Computable general equilibrium (CGE) models, a subject covered well in the *Guidelines*, will be of critical importance but CGE models will likely be wedged in a portfolio of models tracking complex processes. EPA's greenhouse gas lifecycle analysis of various fuels (required by Congress in the Energy independence and Security Act of 2007) is an early example of the daunting analytic challenges associated with forecasting greenhouse gas emissions under various policies. The *Guidelines* should anticipate a changing role for economics amidst the extraordinary complexity posed by climate change and other global processes.

By providing thorough and consistent technical advice regarding the application of benefit cost analysis to environmental problems, the *Guidelines* significantly elevate the quality and transparency of the information upon which environmental decisions are made. We again applaud EPA for developing these *Guidelines* and the Agency's commitment to continually revise and improve them. Indeed, we believe these *Guidelines* could serve as a successful model for all state and federal agencies who undertake benefit-cost analysis in support of environmental decision making. We greatly appreciate the opportunity to provide advice on this draft of the *Guidelines* and look forward to the Agency's response.

Sincerely,

/Signed/

Dr. Deborah L. Swackhamer, Chair EPA Science Advisory Board

/Signed/

Dr. Catherine Kling, Chair SAB Environmental Economics Advisory Committee

Enclosure

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^{*} In order to serve on the Council of Economic Advisors, Dr. Greenstone resigned from the Environmental Economics Advisory Committee in February of 2009 and hence was not involved in writing this Advisory thereafter.

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Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Miller, Designated Federal Officer, Environmental Protection Agency, Washington, D.C.

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This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory committee providing extramural scientific information and advice to the EPA Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report does not reflect the policies and views of the EPA nor of other agencies in the Executive Branch of the federal government. Mention of trade names or commercial products do not constitute a recommendation for use. Reports of EPA SAB are posted at http://www.epa.gov/sab.

Enclosure

Advisory on EPA's Guidelines for Preparing Economic Analyses by the Science Advisory Board

Environmental Economics Advisory Committee

Executive Summary	ES-1
Crosscutting Issues	
Question 1: Policy Options	
Question 2: Baselines	
Question 3: Discounting	
Question 4: Benefits	
Question 5: Mortality Risk Valuation	
Question 6: Social Costs	
Question 7: CGE Models	
Question 8: Distributional Analyses	
Question 10: Economic Literature	
Question 11: Omissions	
Appendix: Compilation of Line by Line Comments from Individual Members.	
References	

Executive Summary

The goal of EPA's Guidelines for Preparing Economic Analyses is to establish a sound scientific framework for performing economic analyses of environmental regulations and policies. Originally issued in 2000, the Guidelines are intended to reflect Agency policy and guide Agency practice on the preparation of economic analyses. EPA's National Center for Environmental Economics recently updated the Guidelines (September 2008) and asked the Science Advisory Board for its input. The SAB Environmental Economics Committee (EEAC) met on October 23-24, 2008 to address the Agency's charge questions on the Guidelines. The Background section of this report discusses some crosscutting issues. Below we provide specific responses to each charge question.

1. Do the published economic theory and empirical literature support the statements in the guidance document on the merits and limitations of the different regulatory and non-regulatory approaches discussed in Chapter 4: Regulatory and Non-Regulatory Approaches to Pollution Control?

Yes, the chapter is supported by economic literature; however it too closely mimics textbook expositions of environmental economics. In order to make it more useful for EPA analysts, we recommend that EPA clarify and discuss the specific role that EPA has in policy design and implementation and provide guidance for economic analysis done specifically within that context. We also recommend a better distinction between efficiency and cost-effectiveness, improvements to the discussion of "cap and trade," a better definition of design standards and technology based performance standards and the inclusion of recent literature on voluntary approaches and the observability of information.

2. Do the published economic theory and empirical literature support the statements in the guidance document on the consideration of the baseline discussed in Chapter 5: Establishing a Baseline?

Yes, this chapter provides very comprehensive guiding principles for specifying the baseline scenario to identify the incremental benefits and costs associated with a policy. We recommend that EPA consider the key dimensions of the economic analysis and any phenomena in the baseline about which there is uncertainty and to construct two or three (rather than more) scenarios that can provide benchmarks for policy analysis.

- 3. Do the published economic theory and empirical literature support the statements in the guidance document on the treatment of discounting benefits and costs discussed in Chapter 6: Discounting Future Benefits and Costs in the following circumstances:
 - a. Are the descriptions of fundamental social discounting approaches, conceptual conclusions and recommendations consistent with the appropriate economic literature on social discounting? Are the correct

conclusions drawn from the respective literatures on discounting for public projects (government spending) and discounting for regulations (government-mandated spending)?

Yes, the descriptions of fundamental discounting approaches, conceptual conclusions and recommendations are consistent with the appropriate economics literature. We do not believe there are significant differences in the approach to discounting for public projects (government spending) and discounting for regulations (government mandated spending). We suggest that the chapter should begin with acknowledgment of the many controversies and complications associated with discounting and orient readers to where in the chapter these are discussed.

b. The Guidelines do not draw a firm conclusion on the extent to which shadow price of capital adjustments are likely to be necessary for most EPA policy analyses. The issue depends greatly on the elasticity of capital supply and EPA plans to pursue additional research on this issue, as noted in the draft Guidelines. Does EPA's conclusion reflect the sense of the literature or can a firmer conclusion be drawn? Does the Committee have suggestions regarding situations where these adjustments would be necessary or unnecessary?

Yes, the EPA conclusion does reflect the sense of the literature. As noted in the chapter, the shadow-price of capital approach is theoretically correct, but the quantitative significance of adjusting for this shadow price is critically dependent on the extent to which EPA regulations displace other investment. In an economy that is open to foreign investment, there may be minimal displacement and so adjustment for the shadow price of investment is negligible. We are pleased to learn that EPA is investigating the elasticity of investment to environmental regulation.

c. While EPA concludes that a rate of 3% is generally consistent with estimates from low-risk government securities, the Agency would like to more firmly establish a rigorous basis for a consumption-based rate. What data and methods would the committee suggest EPA pursue?

We are unable to suggest better data or methods for estimating a consumption-based discount rate, and doubt that alternative credible estimates would differ dramatically from the 3% real rate specified by OMB in Circular A-4. Given the benefits of harmonization of parameter values among federal agencies, we do not encourage EPA to move away from this rate.

d. Chapter 6 recommends adopting an approach to long term discounting based on the work of Newell & Pizer (2003). While EPA recognizes that data may not clearly support a particular statistical model over other alternatives (e.g., random walk vs. mean-reverting), the Chapter concludes that the recommended approach is an improvement over constant discounting. Does the committee believe this is a reasonable conclusion from the economics literature? More specifically, is the recommendation to use a random walk model as a default reasonable given the state of the literature?

No, we believe that calculating present values using the Newell & Pizer approach can be used as one of several alternatives (complemented by appropriate caveats and discussion of the theoretical and empirical issues), but we do not believe it should be relied upon exclusively for reasons provided in the Advisory.

e. EPA has struggled with the question of the length of time an analysis should capture and has arrived at some practical recommendations (see Section 6.1.6.3 and 6.4). Are these recommendations consistent with good economic practices? Does the committee have additional recommendations or insights on this subject?

Yes, the recommendations are generally consistent with good practice. In considering the time horizon an analysis should cover, there is no general answer beyond the answer to the question of what consequences to include: those that may have a quantitatively significant effect on the conclusions of analysis.

4. Do the published economic theory and empirical literature support the statements in Chapter 7: Analyzing Benefits on the merits and limitations of different valuation approaches for the measurement of social benefits from reductions in human health risks and improvements in ecological conditions attributable to environmental policies?

This chapter provides good coverage of the main categories of benefits and the methods used for their estimation. However, it fails to capture a significant amount of recent literature on recreation demand models, combining revealed and stated preference, validity and reliability, valuing mortality and morbidity and ecosystem services. In particular, we urge the Agency to vastly expand its guidance on characterizing and valuing non-monetized ecosystem systems and services. We also recommend expanding the discussion of evaluating studies and data.

5. Chapter 7 includes a brief discussion of the Agency's current approach to mortality risk valuation with more details provided in Appendix B. These sections will be updated when the Agency concludes its efforts to update its mortality risk valuation

approach. In the interim, are the discussions provided in Chapter 7 and Appendix B clear and balanced?

We will refrain from detailed comments on EPA's approach to valuing mortality risk until the Agency's update is complete. In the interim, we recommend EPA consider expanding its literature review and discontinue use of old, discredited wage-risk studies.

6. Does Chapter 8: Analyzing Costs contain an objective and reasonable presentation of the published economic theory, empirical literature, and analytic tools associated with estimating social costs?

Yes. As a suggestion for improvement, we recommend covering non-competitive markets where results can be significantly different. Our detailed comments offer suggestions for other revisions, such as examining three cases: single market analyses, multiple market analyses and general equilibrium analyses.

7. Does Chapter 8 contain an objective, balanced and reasonable presentation of the published economic theory, empirical literature, and analytic tools associated with computable general equilibrium (CGE) models? Is the description of the relevance of these models for economic analyses performed by the EPA reasonable?

Yes. We recommend discussion of the parameterization of CGE models as well as a few minor revisions as discussed in our detailed comments.

8. Does Chapter 9: Distributional Analyses: Economic Impact Analyses and Equity Assessment contain an objective and reasonable presentation of the measurement of economic impacts, including approaches suitable to estimate impacts of environmental regulations on the private sector, public sector and households? This discussion includes, for example, the measurement of changes in market prices, profits, facility closure and bankruptcy rates, employment, market structure, innovation and economic growth, regional economies, and foreign trade.

Yes, this chapter contains an objective presentation of many aspects of economic impact analyses. In our detailed comments, we offer suggestions for minor improvements.

9. Does Chapter 9 contain a reasonable presentation and set of recommendations on the selection of economic variables and data sources used to measure the equity dimensions identified as potentially relevant to environmental policy analysis?

Yes, the main items in assessment equity issues are correctly identified. One limitation is that the main distributional issues discussed in the chapter relate to costs, not benefits. Although it may be more difficult to identify the distribution of benefits, it would seem appropriate to at least represent the ideal case as one in which the equity and impacts associated with both benefits and costs are

considered. We suggest that EPA consider creation of a website to catalog all the data sources.

10. Appendix A: Economic Theory was prepared for those readers who wished to have a better understanding of the economic foundations underlying benefit cost analyses. Does Appendix A summarize the relevant literature in an objective and meaningful way? Are there topics that warrant (more) discussion in this appendix that were otherwise missed?

The Appendix provides a good discussion of core economic principles. As suggestions for improvements, we recommend distinguishing between stock and flow pollutants and inclusion of the concept of "user costs."

11. Please identify and enumerate any inconsistencies you may find across chapters and other issues/topics on which we should provide further elaboration. Also, please identify any definitions provided in the new glossary that are inaccurate or that otherwise need revision.

In general, we would like to see broader discussion of a number of cross-cutting issues. For example, we'd like to see a discussion of the need for transparency in making assumptions and judgments and a discussion of the ways in which biases and errors will matter the most. The *Guidelines* should more frankly acknowledge the "second best" world of most environmental policy problems due to information constraints, political constraints, imperfect competition and market distortions created by taxes and other government policies. The *Guidelines* sorely need case studies and examples to illustrate and make concepts concrete. We underscore our recommendation to provide guidance to analysts for exploring a range of ecological indicators and conceptual models of ecosystems and services.

Background

EPA's National Center for Environmental Economics (NCEE) oversees the Agency's economic analysis of environmental issues. NCEE guides research and development on economic methods, produces EPA's major economic reports and issues guidance for performing economic analysis at the Agency. In this later role, NCEE issued *Guidelines for Performing Economic Analysis* in 2000. These *Guidelines* are meant to provide guidance on economic analysis for those performing or using such analysis, including policy makers, analysts and contractors providing economic reports to the EPA. In 2008, NCEE updated the *Guidelines* to incorporate the most recent advances in environmental economics and asked that the SAB EEAC review the revised document. The SAB EEAC met on October 23 – 24, 2008 to review draft *Guidelines* (September 2008) and respond to NCEE's specific charge questions. This face-to-face meeting was followed by a public teleconference on March 4, 2009 to discuss and amend a preliminary draft Advisory. On August 6, 2009, the SAB provided a quality review in a public teleconference.

In addition to offering specific responses to charge questions, this Advisory also presents some general advice and cross-cutting recommendations. We first identify and discuss these cross-cutting issues below and then proceed to the specific charge questions.

Crosscutting Issues

In general, EEAC would like to see more upfront discussion of the "whys" associated with the material in the *Guidelines*, perhaps in the form of a conceptual overview chapter. It would be useful to explain why a benefit-cost analysis is a valuable undertaking (other than to satisfy a regulation) and why economic impact and equity analyses can be important supplements to benefit-cost analysis, etc. Readers need to see a definition of economic efficiency (allocative and technical, which will help in explaining the relationship between cost effectiveness and benefit-cost analysis) and an explanation of the relationship between economic efficiency, benefit-cost analysis, and cost-effectiveness. We also suggest defining social costs and benefits (as distinct from private costs/benefits), with examples.

In addition to introducing these basic concepts, EEAC would like to see discussion of a number of cross-cutting issues. Environmental policy analysis is inherently an integrated assessment process in which results from different sciences are combined to predict environmental outcomes and their economic consequences. Realistically, a great deal of judgment will have to be exercised by analysts. Given this, the *Guidelines* should discuss the need for transparency in making assumptions and judgments and the ways in which biases and errors will matter the most. For example, if all benefits and costs are understated by about the same amount, the "answer" of whether the benefits exceed the costs will not likely change, however if the costs are biased up and the benefits biased down, the wrong efficiency message could be sent. Care should also be taken to avoid multiple counting of benefits and costs when there are overlapping

regulatory initiatives. Clarity and transparency in the specification of the baseline, including the regulatory initiatives already in place, will enable more accurate identification of the incremental effects of a regulatory initiative.

The *Guidelines* should not underemphasize the value of economic analysis for deregulatory and/or non regulatory purposes. The statement in the *Guidelines* that "formal economic analysis is not required for the selection and implementation of a non-regulatory approach," is true and probably an important point to make. However, the statement could also suggest that economic analysis is less valuable or informative in this case. It is not. Non-regulatory approaches can bring both sizeable costs and benefits and the same can be said for deregulatory decisions. The *Guidelines* should indicate that decisions to deregulate or adopt a non-regulatory approach can be as much informed by economic analysis as those that are purely regulatory in nature.

We recommend that the *Guidelines* incorporate the concept of ecosystem services and its various components, as outlined in the Millennium Ecosystem Assessment (MA) Synthesis Report (2005) and highlight the issue of properly valuing and characterizing ecological systems and services in a benefit-cost analysis. Although OMB Circular A-4 does not require that all economic benefits of a policy be monetized, it does require some scientific characterization of those contributions. Users of the Guidelines should be warned that an inappropriate focus only on impacts that can be monetized can provide misleading policy guidance (as with other cases of unbalanced information). In addition, a strong recommendation should be made to provide quantitative measures of ecological impacts and a qualitative characterization of ecological effects. We urge EPA to consider the SAB's recent recommendation to begin with a conceptual model of the relevant ecosystem and ecosystem services and map those effects to services or attributes that the public values (Valuing the Protection of Ecological Systems and Services, 2009). The SAB report covers a wide range of alternative methods for characterizing, valuing and gauging ecological impacts. We urge EPA to evaluate and determine the appropriate use of these alternative methods and provide much more guidance on characterizing nonmonetized effects.

We understand that EPA is developing a separate chapter dedicated entirely to uncertainty (which we applaud), but the topic is important enough to merit some discussion in the conceptual overview or as a cross cutting issue throughout. It would be useful to point out that uncertainty extends not only to economic information, but to environmental data and modeling. Uncertainty in environmental modeling can be as much or more a source of errors than imperfections in economic assumptions and data. In addition, analysts will be confronted with heterogeneity of data for various reasons (geographic, economic, cultural etc). Recognizing the sources of heterogeneity and deciding how to address them are major analytic decisions. Given that analysts usually face asymmetric information (e.g. on costs vis-à-vis benefits), advice is needed on how to address these information deficiencies. The *Guidelines* might discuss the possibility of ensemble modeling (e.g. hydrology and ecology) and the use of a "weight of evidence" approach, especially for the case of non-monetized ecological effects.

The literature on environmental policy increasingly emphasizes that realizable outcomes will be "second best" due to information constraints, political constraints, imperfect competition, and market distortions created by tax and other government interventions. This emphasis is not adequately reflected in the Guidelines. For example, the theory section focuses on first-best optimal regulation, a framework that provides a baseline but is of limited relevance to regulation of contemporary environmental problems. For example, agricultural nonpoint pollution is now the leading cause of the nation's water quality problems, yet it is less observable than emissions from points sources and far more stochastic. Consequently, the emissions based policies emphasized in the Guidelines are irrelevant inasmuch as they are targeted to conventional point sources. Agriculture is subject to multiple non-environmental policy distortions that must be considered in the measurement of the social benefits and costs of regulating agriculture. Further, agriculture is a source of multiple externalities, some that are positive, some that are negative, that are regulated to varying degree (including not at all) by multiple authorities. The Guidelines should be more adapted to the complexities of contemporary environmental problems.

Given that economics needs to apply to economic analysis, we believe some discussion should be devoted to the allocation of EPA resources in undertaking economic analyses. Where possible, the Agency should consider tailoring the resources spent on the analysis with the size of the proposed regulation's impact. Analysis of the costs of a small project may emphasize simple partial equilibrium analysis, while a larger one may employ both partial equilibrium and CGE models. Similarly, the selection of the number and identity, of say, products or markets to be included in an analysis should consider the benefits and costs from the adding each individual market or product. The evaluation of a large project may justify conducting a new study on willingness to pay (WTP) for the amenities it provides if such information has the potential to change the regulatory decision while a study on the impacts of a smaller project may rely on a benefit transfer analysis if the regulatory impacts are expected to be small. For large regulations with significant impacts, the costs of analysis may be trivial in comparison to potential increases in net benefits if the information results in a change to the final regulation or policy decision.

The *Guidelines* should discuss the analytic challenges posed by emerging environmental problems, particularly climate change. The *Guidelines* are implicitly focused on conventional point source pollutants. Attention to emerging challenges from nonpoint pollutants, changes in carbon and other biogeochemical processes, invasive species, etc. would give the *Guidelines* a more contemporary and forward looking view. The *Guidelines* should point out (and perhaps demonstrate) that the analysis needed for policy decisions to address greenhouse gas emissions will necessarily draw from a complex interdisciplinary suite of studies, data and models. A case in point is the Congressional requirement in the Energy Independence and Security Act of 2007 for EPA to issue a Renewable Fuel Standard based on its calculation of lifecycle greenhouse gas emissions for various fuels. This lifecycle analysis covers the full fuel lifecycle from production to consumption and hence requires an extraordinary synthesis of tools and information from the bio-physical sciences, economics and atmospheric modeling. The

Guidelines could reference this specific example as well as discuss generally the interdisciplinary challenges posed by climate change and other global issues. Given the specter of climate change and other global processes, we expect that future revisions of the Guidelines will need to be broader, describing a kind of regulatory analysis that draws from all the sciences. We note that revisions will be made easier with NCEE's adoption of a loose leaf format to update chapters as appropriate.

Question 1: Policy Options

Do the published economic theory and empirical literature support the statements in the guidance document on the merits and limitations of the different regulatory and non-regulatory approaches discussed in Chapter 4: Regulatory and Non-Regulatory Approaches to Pollution Control?

With a few exceptions, the presentation in Chapter 4 is supported by economic theory and empirical evidence in the published literature. We commend the Agency on a good chapter and offer the suggestions below for improvement.

This chapter provides a good description of policy instruments, much in the same way that a good environmental economics text might. In this regard, we suggest that EPA clarify and discuss the specific role that EPA has in policy design and implementation. For example, the *Guidelines* point out the efficiencies that can accrue with performance-based standards, but do not tell the reader that EPA often does not have the discretion to choose this option, e.g. when "best available technology" standards are required by law. Similarly, after demonstrating that social welfare is maximized by choosing the level of pollution that equates marginal costs with marginal benefits, the *Guidelines* do not inform the reader that EPA is often explicitly prevented from setting standards by this criterion.

We suggest that EPA clarify and discuss the Agency's specific role in policy design and implementation. This would involve stating where EPA has discretion to make decisions in the context of the larger policy arena and then discussing the rationale for the different approaches actually used. That is, EPA primarily issues regulations and those regulations are typically highly prescribed by Congressional mandates as well as the courts' interpretation of environmental laws. On the other hand, EPA analysis can inform the design of future environmental programs by Congress so it is important to retain the discussion of the full suite of policy options described here, but clarifying EPA's discretion in setting policy (even if it varies from statute to statute) would be beneficial. To this end, we recommend that the chapter be organized in two parts: (1) standard treatment of policy options similar to what is currently covered in the Guidelines and (2) discussion of EPA's actual discretion highlighting how economic analysis is used in this narrower context. This would take the chapter beyond the usual treatment of an environmental economics text and make it directly relevant to the agency. One way to explain EPA's role is to show some examples of specific actions (e.g. how design or performance standards are set and/or EPA's role in voluntary programs).

Another topic that would be well suited for discussion in this chapter is the issue of asymmetric information between the regulator (EPA) and the regulated (consumers and industry). This issue has ramifications for the design and efficiency of many kinds of environmental regulations and its importance should be mentioned.

Along these same lines, the chapter discusses maximizing welfare without noting

that in most cases EPA is charged with implementing laws that specify criteria EPA must use. EPA's regulations are not typically based on a calculation of an "optimal" E*, but are more tied to legally-defined criteria. Again, the chapter would be improved by clarifying how EPA's actual authority fits into this paradigm.

This latter point could be nicely integrated into Section 4-1 which could be improved by distinguishing efficiency from cost effectiveness. By dividing the section into two parts: (i) Efficient Level of Pollution (MD = MAC_{aggregate}) and (ii) Cost-Effective Allocation of Pollution – equalize marginal cost across sources (MAC₁= MAC₂= ... = MAC_n), the distinction between optimality of pollution levels and least cost approaches for implementation can be distinguished. Each section will need a supporting graph and should be integrated by showing how aggregate MAC is derived from individual MACs. See Field and Field (2008) and Baumol and Oates (1988) for dividing the discussion this way. Also, in the discussion of the efficient level of pollution, it is important to define social welfare using the underpinnings of Pareto Optimality.

The suggestion in the previous paragraph will allow the use a cost-effectiveness graph to tell the cap and trade story demonstrating its property as a least-cost instrument. Likewise, instead of telling the cap and trade story assuming an optimal level of aggregate pollution for permit allocations, tell the story from the standpoint that a cap and trade can achieve any aggregate level of emissions at least cost. Then, point out that the efficient solution is a special case where the permit allocation is efficient (MD=MAC). Use the same approach for the tax in Section 4.3.2. Again, these points can be illustrated with the point that EPA typically does not set the optimal level of emissions, but can help design and implement instruments to achieve least cost solutions. This discussion can be linked to the asymmetric information issues mentioned earlier by noting that the least cost solution can be achieved, even if the regulator knows nothing about the individual firm costs.

The discussion in Section 4-2 should be clear about the difference between design standards (technology forcing) and technology based performance standards. This could be accomplished by dividing Section 4-2 by (i) design standards and (ii) performance standards and discussing uniform and technology-based performance standards using the cost-effectiveness graph introduced in the previous section. Uniform standards are generally not cost effective but have a low information burden (since one need not know MACs). Technology-based performance standards can be cost effective in principle but have a high information burden (need to know MACs). Regardless of the form of standard, it is always important to recognize that different options may yield different levels of environmental improvement which need to be adequately accounted for in analysis that compares design with performance standards.

We recommend the section on taxes include some discussion of what is taxed: the pollutant, an input, a process, or something elsewhere? In principle it should be placed on damages (a true Pigouvian tax), but administrative and monitoring costs may suggest targeting the tax elsewhere. Taxing gas may be much easier and probably as effective as

^{*} MD = marginal damages. MAC = marginal abatement cost

taxing damages from auto emissions. Similar principles apply to permit trading, so although EPA lacks the legal authority to levy a tax, a discussion of targeting would have broad application.

On this point more generally, note that policy design is dependent on observable and available information. For example if policy makers can not observe actual pollution levels, but inputs and practices that cause pollution can be observed and there are reasonable estimates on the relationship between the input, technology use and the pollution level, then taxes or regulations may be based on the imputed pollution levels. Policies should be designed to best take advantage of the available knowledge. In particular identifying sources of heterogeneity among users and knowing how they affect pollution levels can be central to policy design. The proliferation of geographic information systems and remote systems to obtain data provide new opportunities for policy design. Studies suggest that there is a significant efficiency gains from policies that adjust to observed heterogeneity relative to uniform policies (Xabadia et. al., 2008). Availability of new sources of or means to obtain information may lead to redesign of policies – for example, availability of a technology that allows cheap monitoring of pollution may lead to regulation on taxation based on annual pollution rather than imputed pollution. Policy makers should reassess policy design and implementation as technology progresses. (See Xabadia et. al., 2008) as one example. There are many other papers that demonstrate the efficiency gains from increased targeting.

As noted in the cross cutting issues discussion earlier, we suggest adding discussion of second best solutions covering imperfect markets, pre-existing policies, asymmetric information, and so forth. In this chapter, EPA could incorporate the implications of imperfect markets and other second best solutions in the relevant sections and refer readers to the material in the cross cutting issues discussion. Examples include monopoly, price supports in agriculture, pre-existing environmental policy, recent biofuels legislation, etc.

When the section on market based regulations is introduced, it would be helpful to explain that these controls tend to be least costly, have a low information burden on regulators, provide incentives for technological advancement, and so forth. Monitoring and enforcement costs and other administrative costs, of course, can favor direct regulation.

It would be helpful to mention that information disclosure strategies can allow the market to create incentives for pollution control (following Coase) with the victims directly signaling their preferences to firms. But these are most likely to work when there are contractual obligations between polluting firms and affected parties (e.g. consumers/workers) and more difficult to work when they affect third parties (see Tietenberg, 1998). Also it should be mentioned that credibility of information is important. Information disclosure can lead to inefficient outcomes when information is not credible (see Brouhle, K. and M. Khanna, 2007).

The section on subsidies should mention that many subsidies in existence, such as

those in agriculture, car manufacturing, oil and gas, forestry, and so forth, are not corrective subsidies designed to correct externalities and may in fact worsen externalities. This could also be discussed in the second best discussion.

An area of omission is the relatively new literature regarding the effectiveness (or lack there of) of voluntary approaches (Morgenstern and Pizer, 2007 and National Research Council, 2002, as well as a number of journal articles). These should be noted and made a part of the section on voluntary controls. Assessment of the effectiveness of a voluntary program in the literature has been based on estimates of participation rates and the reduction in pollution achieved by the program relative to that in the absence of the program. A comparison of the costs of pollution control under a voluntary program relative to that under alternative policy options to achieve the same level of pollution control would be valuable for assessing the cost-effectiveness of voluntary approaches.

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Question 2: Baselines

Do the published economic theory and empirical literature support statements in the guidance document on the consideration of the baseline discussed in Chapter 5: Establishing a Baseline?

Yes, the approach described in the *Guidelines* to establish a baseline is supported by economic theory and empirical literature in this area. This chapter provides very comprehensive guiding principles for specifying the baseline scenario to identify the incremental benefits and costs associated with a policy. It describes the methods for defining a scenario that does not include the policy (baseline scenario) and one that does include the policy; that is, a 'with' and 'without' policy comparison. It suggests that in some cases it may be appropriate to specify multiple baseline scenarios to describe the state of the world in the absence of a regulation. While we agree with the need to consider more than one baseline when it is difficult to define a unique state of the world in the absence of the policy with a high degree of certainty, the number of baselines constructed should be limited to as few as possible that cover the reasonable baseline alternatives. In some cases it may also be appropriate to use probabilistic analysis with a continuum of baselines to provide the benchmark for policy analysis.

Additionally, in defining the baseline scenario, analysts need to consider which sectors should be included. Although the direct effects of the policy may be focused on a few sectors, indirect impacts can be significant and should be measured. It is therefore important to establish which other sectors of the economy may be affected, directly or indirectly, by a policy and should be included in the baseline. Some policies can have pecuniary effects that will affect the opportunity costs of implementing that policy. This is particularly relevant when the pecuniary costs occur in inefficient markets; in such cases the opportunity costs of a policy can differ from the monetary costs of the policy (see Boardman et al., 2006).

The assumption of full compliance with the existing and newly enacted regulations does not appear realistic. Instead, compliance rates in the baseline should be based on available factual evidence. Assumptions about compliance rates in the policy scenario should also be based on a realistic assessment. These rates are likely to depend on how stringently the policy is implemented and enforced.

We also suggest including a text box distinguishing the induced innovation effects of regulation from the Porter Hypothesis. It would be useful to clarify what the Porter hypothesis is (i.e., define it) and to distinguish between its strong form and weak form. The strong form of the Porter Hypothesis states that regulations can induce innovations that can lead to cost savings that are larger than the costs of the innovation and compliance. The weak form of the Porter Hypothesis simply states that environmental regulations lead to innovation. We agree with the statement that there is only limited evidence of the strong version of the Porter Hypothesis; some references to the literature providing situations in which it might hold (such as in the presence of imperfect information, high search costs, etc.) could be added. There is much more evidence to

support the weak form of the Porter Hypothesis (which is similar to the induced innovation hypothesis) and this should be made clear.

Question 3: Discounting

Do the published economic theory and empirical literature support the statements in the guidance document on the treatment of discounting benefits and costs discussed in Chapter 6: Discounting Future Benefits and Costs? (sub parts for this charge are copied below)

Overall, the chapter provides a clear and comprehensive discussion of discounting. This chapter has been updated to reflect much of the current thinking on discounting in the context of environmental decision making and we applaud EPA for doing so. We begin with some general comments then respond to each of the subparts of the charge question below.

Discounting is an important, complicated, and controversial topic. The results of an economic evaluation can be extremely sensitive to the discounting approach that is used, especially for projects where significant benefits and costs are incurred at widely disparate times (e.g., climate change mitigation; nuclear-and hazardous-waste storage). We suggest that the chapter begin with an acknowledgement of these issues and orient readers to the parts of the chapter in which they are discussed. (At present, readers must wade through the necessary but less interesting section on mechanics of discounting before grappling with these topics). Some of the issues that could be highlighted include: (a) differences between relatively short run ("intra-generational") and long run ("intergenerational") discounting that arise in part because inter-generational contexts necessarily involve a greater distributional aspect and future generations are not represented in markets; (b) sensitivity of results to choice of discounting approach and discount rate; (c) distinction (and frequent confounding) of efficiency and distributional issues; (d) distinction between utility vs. consumption discount rates; (e) "ethical" or prescriptive vs. descriptive approaches to selecting a discounting approach; (f) uncertainty about future economic growth and other conditions; (g) constant vs. nonconstant (e.g., hyperbolic) discounting approaches; and (perhaps) (g) future changes in relative prices that imply different consumption discount rates for different goods.

Although it is implicit in the text, the distinction between discounting to reflect differences in timing of consequences and discounting to adjust for inflation should be emphasized. It is conventional (and recommended) to measure effects in real dollars and use a real rather than nominal discount rate to account for differences in timing. (Note that if inflation rates differ across goods, the real discount rate depends on the inflation adjuster that is used.)

There is much confusion in the literature (and in policy discussion) about the determinants of the discount rate, e.g., whether it is a result of preferences for consumption sooner rather than later or of the productivity of capital investment. At least for "intra-generational" discounting, the (consumption) discount rate (or rates) is best understood as being determined by a price (or prices) – the interest rate(s) at which consumption can be shifted through time (e.g., consumers may shift consumption to the future by consuming less and investing more, and may shift consumption toward the

present by saving less or borrowing). The interest rate is determined, like other prices, as a market equilibrium between agents who wish to shift resources through time. Consumers adjust current and future consumption so that their indifference curves for current and future consumption are tangent to the market opportunities for shifting consumption through time (determined by the interest rate). As noted in the chapter, a variety of interest rates exist (associated with riskiness of investment and time horizon) and there are wedges between private returns associated with taxation of investment returns and other factors. For longer-term "inter-generational" issues, the interpretation of the discount rate as a price is less natural, because market interest rates for periods longer than about 30 years rarely exist and future generations' do not directly participate in current markets, so their preferences may not be adequately represented.

In the discounting chapter or elsewhere, it may be useful to highlight the distinction between positive (i.e., descriptive) and normative perspectives (i.e., prescriptive) justifications for economic evaluation and the tension between these. Economic evaluation is normative in that it is conducted in order to compare alternative policies, yet it is positive in that it attempts to identify the policy that maximizes the perceived welfare of the affected population. Behavior that differs from Economic evaluation is sometimes justified as identifying policies to maximize (or at least increase) social welfare, which is normative because it is based on an assumed social welfare function. In contrast, economic evaluation is also sometimes justified as identifying policies that produce potential Pareto improvements, i.e., policies such that all members of the affected population would prefer to the alternative policy (if combined with appropriate compensation payments). Policies that increase social welfare are not necessarily potential Pareto improvements, that those that are potential Pareto improvements need not increase social welfare. Moreover, individual behavior that is inconsistent with maximization of individual utility (e.g., behavior that is dynamically inconsistent, perhaps because it accords with hyperbolic discounting) creates a tension between these perspectives and raises questions about how to conduct the analysis. See Hammitt (2009, 2002) and Portney (1992).

a. Are the descriptions of fundamental social discounting approaches, conceptual conclusions and recommendations consistent with the appropriate economic literature on social discounting? Are the correct conclusions drawn from the respective literatures on discounting for public projects (government spending) and discounting for regulations (government-mandated spending)?

The descriptions of fundamental social discounting approaches, conceptual conclusions and recommendations are consistent with the appropriate economics literature. We do not believe there are significant differences in the approach to discounting for public projects (government spending) and discounting for regulations (government-mandated spending) – in both cases, there can be a need to account for differences in timing of benefits and costs and the relevant conceptual basis is social valuation of consequences at different points in time.

b. The Guidelines do not draw a firm conclusion on the extent to which shadow price of capital adjustments are likely to be necessary for most EPA policy analyses. The issue depends greatly on the elasticity of capital supply and EPA plans to pursue additional research on this issue, as noted in the draft Guidelines. Does EPA's conclusion reflect the sense of the literature or can a firmer conclusion be drawn? Does the Committee have suggestions regarding situations where these adjustments would be necessary or unnecessary?

As noted in the chapter, the shadow-price of capital approach is viewed as theoretically correct, but the quantitative significance of adjusting for this shadow price is critically dependent on the extent to which EPA regulations displace other investment. In an economy that is open to foreign investment, there may be minimal displacement and so adjustment for the shadow price of investment is negligible. We are pleased to learn that EPA is investigating the elasticity of investment to environmental regulation.

c. While EPA concludes that a rate of 3% is generally consistent with estimates from low-risk government securities, the Agency would like to more firmly establish a rigorous basis for a consumption-based rate. What data and methods would the committee suggest EPA pursue?

We are unable to suggest better data or methods for estimating a consumption-based discount rate, and doubt that alternative credible estimates would differ dramatically from the 3% rate specified by OMB in Circular A-4. Given the benefits of harmonization of parameter values among federal agencies, we do not encourage EPA to move away from this rate.

d. Chapter 6 recommends adopting an approach to long term discounting based on the work of Newell & Pizer (2003). While EPA recognizes that data may not clearly support a particular statistical model over other alternatives (e.g., random walk vs. mean-reverting), the Chapter concludes that the recommended approach is an improvement over constant discounting. Does the committee believe this is a reasonable conclusion from the economics literature? More specifically, is the recommendation to use a random walk model as a default reasonable given the state of the literature?

We do not recommend using the Newell and Pizer approach as a default but as one of the alternatives for inter-generational discounting. Since the declining discount rates under this approach are sensitive to modeling assumptions, transparency in the assumptions underlying the determination of the discount rates used will be important as will comparisons with other alternatives.

The conceptual idea, identified by Weitzman (1998, 2001), should be clearly stated in the chapter: uncertainty about the appropriate discount rate to use has a nonlinear effect on the discount factor that varies with the time horizon. Specifically, because the discount factor for time t, $[1/(1+r)]^t$, is a nonlinear function of the discount rate r, the expected discount factor is not equal to the discount factor obtained by substituting the expected value of r in this formula. For small t, the difference between

the two discount factors may be small, but as t becomes arbitrarily large the expected discount factor approaches the discount factor corresponding to the minimum possible value of r weighted by the probability assigned to that minimum value. Weitzman developed a distribution for r by polling economists and derived a corresponding schedule of certainty-equivalent discount rates (the discount rate associated with the expected discount factor); Newell and Pizer built on his work by conducting an empirical analysis of historical interest rates. Their results are naturally sensitive to modeling choices about the intertemporal correlation of rates.

Our concern about this approach is the following. In a world with no uncertainty about the discount rate, one can compare streams of consequences in terms of their present values or their future values at any future date. The choice between these perspectives has no effect on the ranking: because the present value of a policy is simply the present value of the policy's future value (i.e., the future value discounted to the present), whichever policy has the larger present value will also have the larger future value.

In contrast, when the discount rate is uncertain, the rank ordering of policies by present values and future value may differ. As shown by Weitzman, for large t the present value is dominated by the small discount rates. But the future value is dominated by the large discount rates (i.e., the expected value of the factor used to convert present consequences to their future value, $(1 + r)^t$, is dominated by the largest possible values of r). This dependence of the evaluation on what appears to be an arbitrary choice of perspective suggests a problem with the analysis that urges caution in its application and invites further investigation (Gollier, 2004; Hepburn and Groom, 2007). Given this concern, we urge caution in interpretation of results calculated using the Newell and Pizer approach and encourage further investigation.

e. EPA has struggled with the question of the length of time an analysis should capture and has arrived at some practical recommendations (see Section 6.1.6.3 and 6.4). Are these recommendations consistent with good economic practices? Does the committee have additional recommendations or insights on this subject?

In considering the time horizon an analysis should cover, there is no general answer beyond the answer to the question of what consequences to include: those that may have a quantitatively significant effect on the conclusions of analysis (as noted in Section 6.1.6.3). With positive discounting, the influence of consequences decreases with their temporal distance; unless the probability-weighted magnitudes of consequences grow sufficiently rapidly with time, their effect on the analysis will become negligible. In general, there is no method for knowing whether a consequence may be sufficiently important to merit inclusion except by including it and testing for its effect. For this purpose, a rough estimate or upper bound is often sufficient. As noted in the text, many exogenous factors are likely to influence the date at which the effects of the policy become negligible (e.g., technological innovation or policy change).

Question 4: Benefits

Do the published economic theory and empirical literature support the statements in Chapter 7: Analyzing Benefits on the merits and limitations of different valuation approaches for the measurement of social benefits from reductions in human health risks and improvements in ecological conditions attributable to environmental policies?

This chapter provides good coverage of the main categories of benefits of environmental policies and regulations, and of the methods used to estimate them. The chapter might flow better if the discussion of the main categories of benefits was more concise, and more details about the valuation of these impacts were offered in the overview at the end of the chapter.

Chapter 7 falls significantly short of capturing a considerable amount of recent literature on benefits. In the following pages, we identify a number of areas where the literature of the past decade or so is not adequately reflected in the chapter. We have not made an effort to be exhaustive in recommending additions, but rather to identify areas as obvious omissions. In general, the Handbook of Environmental Economics published by North Holland in 2005 would be an excellent starting place. More specifically, the literature in the following areas needs to be updated:

- Recreation Demand Models. A great deal of work published in the last decade on random utility maximization (RUM) and Kuhn-Tucker models have taken these approaches beyond the descriptions provided in the Guidelines. Updated approaches to valuing the opportunity cost of time, identification of choice sets, and other aspects of recreation demand should also be included. Potentially useful sources for journal research that should be reflected in the Guidelines can be found in the collection of articles in Herriges and Kling, (2008), among other works. In addition to covering methods for valuing natural resources that have recreational use, this volume is also a good source for articles related to hedonics and locational equilibrium models. For more theoretical treatment cite Bockstael and McConnell, (2008). For more practical discussion cite Champ et. al. (2003).
- 2. Combining Revealed Preference (RP) and Stated Preference (SP). A revised draft of this chapter should discuss work over the past decade that has sought to combine revealed and stated preference methods. This has been an area of significant interest as researchers have attempted to understand how the strengths of each approach might be combined to improve the performance of welfare estimators. On the theoretical front, Herriges and Kling, (1999) raise the question of whether revealed preferences can ever accurately estimate welfare for quality changes when weak complementarity cannot be assured.
- 3. Stated Preferences: Validity and Reliability. A significant amount of recent work related to stated preference approaches is not reflected in the Guidelines.

 Understanding whether people over- or under-state their actual preferences for a non-marketed good when asked a hypothetical question and whether approaches to

mitigate these effects are successful remain important researchable questions. Considerable work on this question has been undertaken beginning with studies such as Bohm's (1972) experimental lab study which compared bids in hypothetical and real experimental markets that elicited subjects' stated value to sneak preview a Swedish television show. His results suggest that people moderately overstate their real values when asked a hypothetical question. Other early work includes the studies by Bishop and Heberlein, (1979), Duffield and Patterson, (1992), and others who compared stated preference estimates to those obtained from actual transactions.

Subsequent research has included both field and laboratory experiments. For instance, List and Gallet (2001) report the results of a meta-analysis to determine whether important experimental parameters systematically affect the relationship between hypothetical and real responses, concluding that certain elicitation methods that yield less hypothetical bias than others. Others (e.g., Cummings and Taylor, (1999), List, (2001), Lusk and Prevant, (2008), etc.) have studied hypothetical bias and incentive compatibility focusing specifically on the dichotomous choice elicitation format in contingent valuation. These and other references addressing this literature should be discussed in the *Guidelines*. Remaining research questions and needs should also be identified.

A final area in which SP validity and reliability research has appeared is in the arena of choice experiments. Although many choice experiment-based studies are not conducted in ways that would preserve incentive compatibility, some limited evidence exists suggesting little or no hypothetical bias when estimating marginal attribute values (see List et al., 2006, and Lusk and Norwood, 2005)

- 4. Valuing Mortality. There are a number of studies that need to be updated in this area, please see charge question #5 for specifics.
- 5. Valuing Morbidity. The *Guidelines* should provide a sense as to whether the research community is satisfied with existing estimates of morbidity benefits. Is the usual approach—symptom days—still judged acceptable? Likewise, this section points out that frequently used approaches, such as the cost-of-illness or averting expenditures, do not capture the full WTP to avoid an episode of illness. It would be useful to note that some studies (e.g., Rowe and Chestnut, 1985, and Alberini and Krupnick, 2000) have estimated that total WTP can be two to four times as large as the cost of illness, even for minor acute respiratory illnesses (as in Alberini and Krupnick's case).
- 6. Ecosystem Services and Benefits Assessment. The literature review is outdated, and there are no examples of recent studies that attempted to place a value on ecosystems and ecosystem services. It would be useful to know which measures of ecological system function was used in those studies, whether market or non-market valuation approaches were used, and what the strengths or shortcomings of these studies were.

Ecosystem services encompass a broad array of goods and services, ranging from standard market goods like agricultural products to far more complex and less well identified services such as nutrient cycling. Valuing the more complex ecosystem services is very challenging because it requires sequential linkages from the policy of interest to the direct effects on organisms to the associated indirect effects through changes in the functioning of ecosystems to the resulting changes in services and finally to the associated social values. Our understanding of each of these elements is rudimentary in some cases. Yet, we need to develop analyses to support policy decisions in spite of the many uncertainties.

This document should provide more extensive guidance on how to carry out valuation of ecosystem services within the context of policy decisions that EPA needs to make. A variety of techniques are available that can provide useful input to policy within the context of less than complete knowledge. In addition to standard cost-benefit methods, these approaches include cost effectiveness analyses, choice-based methods (e.g., Opaluch et al, 1993; Unsworth and Bishop, 1994; Adamowicz et al, 1998), etc. The report should also draw from recent reviews, including EPA SAB (2009) and the National Research Council (2004).

The report should address important challenges facing the practitioner, including: What does valuation of effects on ecological systems share with valuation of other benefits? In what way is it different? What are unique difficulties when valuing ecosystems or ecosystem services? What approaches are available in face of the many uncertainties?

As mentioned in the discussion of cross-cutting issues, we urge the Agency to vastly expand its guidance on characterizing non-monetized benefits. We recommend that the *Guidelines* incorporate the concept of ecosystem services and its various components, as outlined in the *Millennium Ecosystem Assessment (MA) Synthesis Report* (2005) and highlight treatment of ecological systems and services in benefit-cost analysis. Users of the *Guidelines* should be warned that an inappropriate focus only on impacts that can be monetized can provide misleading policy guidance (as with other cases of unbalanced information). In addition, a strong recommendation should be made to provide quantitative measures of ecological impacts and a qualitative characterization of ecological effects. These quantitative measures and qualitative descriptions are needed whether or not benefits can be monetized. We note that EPA's Office of Research and Development has an extensive Ecosystem Services Research Program that may be an excellent resource for economists who need information ecosystem impacts for economic analysis.

We urge EPA to consider the SAB's recent recommendation to begin with a conceptual model of the relevant ecosystem and ecosystem services and map those effects to services or attributes that the public values (*Valuing the Protection of Ecological Systems and Services*, SAB, 2009). The SAB report

covers a wide range of alternative methods for characterizing, valuing and gauging ecological impacts. We urge EPA to evaluate and determine the appropriate use of these alternative methods and provide much more guidance characterizing non-monetized effects. Another recommendation from the SAB report that could be appropriated for the *Guidelines* is to label aggregate monetized benefits as "total monetized economic benefits," not "total benefits." We believe the SAB report provides other useful examples relevant to the *Guidelines*.

In addition to updating the literature in the area just enumerated, we recommend expended treatment of the discussion about assessing studies and data. We applaud EPA's discussion of validity concepts (page 7-41) as the basis for choosing among studies for inclusion in a benefit-cost analysis, but the treatment of the validity and reliability of estimation methods is uneven. Much of the discussion about validity centers on stated preference methods. However, we feel that due to (usually untested) assumptions that they make about individuals' perceptions of environmental quality and identification of effects, revealed preference methods should be scrutinized for quality and validity, as should CGE models.

The material in Sections 7.4.2.3 "Considerations in Evaluating Stated Preference Results" and 7.4.3 "Benefits Transfer," could be used as a starting point. For example, the validity tests (content, criterion and convergent) discussed on 7-41-7-42 apply to all types of studies, not just stated preference, as do various biases associated with survey non-response (7-42-7-43). Other validity concepts that should be discussed include:

- Internal Validity: is there plausibly exogenous variation in the variable of interest (the one capturing health risks or environmental quality)?
- External Validity: Can the study's results be generalized to the overall population of interest? Can the study's results be generalized to the time period of interest? Is the study's treatment relevant for the program that is under consideration?
- Theoretical Validity: Can the study's results be interpreted as a measure of willingness-to-pay (WTP) (or a bound on WTP)?

A discussion of the trade-offs between revealed and stated preference approaches could be very helpful to readers. EPA should note that flaws of both stated preference (SP) and revealed preference (RP) should be considered when evaluating studies and performing regulatory analysis. For example, most hedonic properties, compensating wage differentials and other revealed preference studies assume, without testing, that people know the correct risks or level of environmental quality. These studies will often estimate the willingness to pay or accept for changes that do not match well the policy change under consideration. In contrast, validity questions related to stated preference studies are a limitation that should be not disguised or diminished. It would be useful to emphasize that judgment is essential to good analysis and that the results from stated (and revealed) preference studies should be carefully assessed with economics and commonsense basics. For example, is WTP for a change in environmental quality a reasonable

fraction of one's income? Does it increase in predictable ways as income increases, and are the estimates of income elasticity of WTP reasonable and consistent with other evidence?

Chapter 7 states that the Agency should use benefit transfer only as a last resort, when time and budget constraints do not allow original benefit estimation. We agree, but the reality appears to be that benefits transfer is the most common approach to completing a benefit-cost analysis. If correct, this should be acknowledged. Further, the exposition of the possible benefit transfer techniques reads somewhat mechanically and does not clearly discuss the underlying assumptions. For example, unit value transfer presumes that the original good, the characteristics and the tastes of its population of beneficiaries are the same as the policy good/locale. When a value function transfer is done, it is implicitly assumed that the population of beneficiaries to which we are applying the transfer has potentially different characteristics, but similar tastes, as the original one.

EPA should distinguish the criterion used to evaluate an original study from those that can be used to evaluate a study for use in benefits transfer. Given the importance of the process of "benefits transfer" in benefit-cost analysis performed for EPA, separate guidelines for analysts on to how to evaluate studies to use in a benefits transfer is warranted. In doing so, we note that there is an extensive literature that provides guidance on benefits transfer that the Agency can draw upon such as the special issues in *Ecological Economics*. Some issues that are likely to belong in such a set of considerations include: similarity of environmental good valued in original study to environmental good being valued in benefits transfer; similarity of original study sample to population of interest in the policy/regulatory setting; and overall quality of the original study benefits (i.e., the set of considerations in the above list "benefits – original studies").

The document discusses meta-analysis as one way of conducting benefit transfer. Almost two years ago, two meta-analysis experts briefed the EEAC about meta-analysis. They reminded us that a meta-analysis seeks, at best, to establish whether certain aspects of study design and execution influenced final values, and its results should be interpreted with caution. They offered a number of recommendations, warning against the "ecological fallacy" and against pooling values from studies conducted with extremely different methods. The chapter would benefit from reviewing the main lessons from that presentation.

Question 5: Mortality Risk Valuation

Chapter 7 includes a brief discussion of the Agency's current approach to mortality risk valuation with more details provided in Appendix B. These sections will be updated when the Agency concludes its efforts to update its mortality risk valuation approach. In the interim, are the discussions provided in Chapter 7 and Appendix B clear and balanced?

We will refrain from extensive comments on mortality risk valuation until the Agency's update is complete. In the meantime, we recommend the Agency consider expanding discussion in the following manner to improve the balance in the current version of this section.

The literature review about methods used for valuing mortality risks should be updated. Generally, the Chapter does a good job recognizing the advantages and limitations of using the two main metrics in mortality benefits valuation (the VSL and the VSLY) and of the different methods used for estimating them (revealed preference, usually in the context of occupational risk, and stated preference). It also does a good job discussing factors—such as age and pre-existing conditions—that matter with environmental exposures and may affect the VSL. The chapter does, however, overlook Viscusi and Aldy (2007), who look at age and the VSL in a wage-risk context. It could also include discussion of alternative methods for estimating VSL such as the "chained" approach linking WTP to reduce non-fatal injury with risk tradeoffs between fatal and non-fatal injury (Carthy et al., 1999).

Despite its careful discussion of the limitations implicit in using the VSL estimated from compensating wage studies when valuing mortality risks associated with environmental exposures, Appendix B and much of EPA's current practice continue to rely on old wage-risk studies. All of these wage-risk studies use old data, i.e., risk levels that are no longer likely to exist and obsolete preferences for risk and income; they are based on cross sections of data, do not control for self-selection into risky jobs and for heterogeneity in preferences for risk and income, and contain a massive measurement error in the risk variable. Better studies to discuss that control for unobserved heterogeneity as well as use better risk measures are Kneisner, et al. (2006), Viscusi (2004), Kochi (2008), among others.

The Guidelines should discuss the research concerning the VSL for specific causes of death that are associated with environmental exposures—cancer and cardio-and cerebro-vascular illnesses (e.g., Gayer et al., 2000, 2002; Davis, 2004; Johannesson and Jonsson, 1991; Alberini and Chiabai, 2007). The Guidelines should also discuss research needs in this area. A number of studies using revealed preference methods infer values for risks related to the agency's policies (e.g., Davis, 2004, Gayer et al. 2002, Greenstone and Gallagher (2008), Ashenfelter and Greenstone (2004), Gayer et al. (2000)) and others. Likewise, there are newer stated preference studies that infer values

for risks related to agency's policies that should be referenced (see Krupnick (2007) for examples).

In several places, the Agency refers to the importance of "the impacts of risk and population characteristics" on valuation estimates (e.g., p. 7-6, line 36; p. 7-8, line 31-43; p. B-4, lines 29-32), yet the discussion is generally focused on population characteristics. The agency should consider adding more discussion about the impact of risk characteristics on valuation, the newer literature valuing the events of relevance to environmental policy, and relate these issues to its recommended default value.

Question 6: Social Costs

Does Chapter 8: Analyzing Costs contain an objective and reasonable presentation of the published economic theory, empirical literature, and analytic tools associated with estimating social costs?

In general, the Chapter does contain an objective and reasonable presentation of economic theory, literature and analytical tools. While generally quite well done, we found several areas where improvements could be made.

At the end of Section 8.3.1.3 Discounting, the *Guidelines* state "In calculating firms' private costs, e.g. the internal cost of capital used for pollution abatement, analysts should use a discount rate that reflects the industry's cost of capital." While this quote is correct, we fear that it could be misinterpreted to suggest that costs and benefits might be legitimately discounted at different rates within a single analysis. Doing so could lead practitioners to make significant errors. For example, an analysis with different discount rates applied to public and private costs could justify a project whose private costs greatly exceed its public cost savings when both occur at the same time period in the distant future. Yet, as the time approaches, this decision would be reversed, implying a form of time inconsistency. The Guidance should be written to make clear that such a practice would not be appropriate.

The beginning of the chapter indicates that costs are usually viewed as straightforward to estimate, but in fact estimating costs presents many challenges. For example, estimating costs of new regulations requires forecasts many years into the future. As pollution control technologies are implemented over time, firms can learn from experience and the development of new technologies may reduce the cost of achieving the standards. At the same time, *ex ante* cost estimates may be based on the assumption that everything works as anticipated, but in practice deviations from expected outcomes often mean higher than anticipated costs. These challenges can be exacerbated since industry often has more information about costs than regulators and are likely to have the incentive to overstate their costs. All these arguments reinforce the report's indication that measuring costs are not at all straightforward, nor are cost estimates "hard" numbers.

The report differentiates between partial equilibrium analyses which model a single market or a small number of markets, versus general equilibrium analyses that model the entire economy. The Chapter might be better organized by examining three cases: single market analyses, multiple market analyses and general equilibrium analyses. Significantly different challenges are faced when carrying out multi-market partial equilibrium models than single market models, and it might make the explanation more clear.

Also, some additional guidance would be helpful on carrying out multimarket partial equilibrium models (e.g., Section 8.1.2, page 8-5). For example, the report could indicate the conditions under which multimarket models are likely to be necessary, and

how multimarket analyses should be carried out. The Just, Hueth and Schmitz textbook provides a thorough treatment of these issues, and could be both the source of information for the document summary and an excellent reference for further information.

It is important to note that it is not simply the number of markets that are affected directly by a regulation, but also their size and influence on the economy that determine whether partial equilibrium analysis is adequate. Indeed, the first example under CGE (Sec 8.1.2) is of a single but large market (electric utilities). Similarly, a partial equilibrium analysis of a significant change in "the labor market" is unlikely to be adequate, given its influence on nearly all markets in the economy. It might also be worth noting that definition of "a market" is not always clear cut. Is "the labor market" one or a large collection of segregated markets with somewhat permeable boundaries, by age, education, experience, geography, etc.?

On page 8-4, immediately below the figure, the text states "While in reality at least part of the compliance cost will likely be spent on abatement-related purchases from other industries – and is thus not necessarily a loss to society – in this market, the deadweight loss resulting from the regulation is lost completely." It should be made clear that expenditures in other markets are losses to society except for the portion that is a quasi-rent. We are concerned this passage could be interpreted as expenditure per se in other markets are not losses to society. Again, the Just, Hueth, and Schmitz (2005) textbook is an excellent source for appropriate accounting of multimarket effects.

In general, the treatment in the report focuses too much on perfectly competitive markets, and provides too little discussion of non-competitive market environments. In our introductory comments and in response to Charge Question 1, we discuss the need to incorporate real world "second best" conditions in the Guidelines. With respect to costs, results will differ significantly in a non-competitive market, or in a market where there are other distortions. In general, a complex game theoretic formulation is needed to assess effects in markets that are not perfectly competitive.

Question 7: CGE Models

Does Chapter 8 contain an objective, balanced and reasonable presentation of the published economic theory, empirical literature, and analytic tools associated with computable general equilibrium (CGE) models? Is the description of the relevance of these models for economic analyses performed by the EPA reasonable?

Overall, the discussion of the structure and use of computable general equilibrium models in Chapter 8 is concise and very good. It clearly summarizes the design and structure of CGE models, their strengths and weaknesses, and the role of such models in economic analysis at EPA.

The only major topic the section does not discuss is the parameterization of CGE models. Some use behavioral parameters estimated econometrically from extensive time-series data, while other models use parameters calibrated to a single input-output table or taken from the literature. Estimation is clearly preferable where adequate data exist. One of the principal benefits of general equilibrium modeling over input-output analysis is its ability to capture substitution in production and consumption, so it is important that the relevant elasticities be tied as closely as possible to the historical record. A paragraph on parameterization should be added to the section. A brief discussion of parameterization should be added to Section 8.4.4 on Input-Output analysis as well.

Secondly, the *Guidelines*' discussions of CGE modeling in general and the concept of general equilibrium welfare analysis in particular should be expanded to address the role of models that introduce pollution (or equivalently environmental services) in non-separable specifications for consumer preferences. Such specifications introduce the prospect for feedback effects where policies to reduce externalities lead to changes in the demand for market goods and then in turn the amount of pollution giving rise to the externalities. These responses "feedback" and affect the demands for market goods. The process can be expected to continue with the models describing systems where the market and non-market interactions affect the ultimate market equilibrium. It is important to draw distinctions between sorting models with multiple markets and what might be described as extended partial equilibrium analyses and CGE models. Recent advances in both types of models allow EPA to consider using these structures to assess when the changes associated with their policies would be large enough that conventional practices that assume away general equilibrium effects need to be modified or at least qualified. There is sufficient research that the Guidelines can begin to introduce candidate procedures for addressing these issues.

The section would benefit from a few minor revisions as well. First, the discussion at the beginning of Section 8.1.2 should emphasize that the need for general equilibrium analysis depends on the scope of the policy's effects rather than just the number of markets. A policy might have significant effects in a single market, but if the market is large enough (the labor market, for example), general equilibrium analysis would still be warranted. Similarly, a policy affecting a large number of very small markets might be adequately addressed by partial equilibrium analysis.

A second minor revision is that the discussion of the benefits of dynamic models should be expanded slightly. Not only are such models useful for capturing saving and investment effects, they can also be used to examine policies that themselves change over time—becoming more stringent, for example. In addition, models based on intertemporal optimization by the underlying agents can also capture anticipation effects: changes in behavior occurring when policies are announced that don't take effect until some point in the future.

A third minor point is that the discussion of the ability of CGE models to capture transition costs should be expanded slightly and the conclusion that they cannot capture such costs should be refined. It is true that many models are inappropriate for short run analysis because they assume that capital and labor are completely mobile between sectors, and because they typically use substitution elasticities that reflect medium to long. run behavior. However, those are characteristics of existing models rather than the methodology itself. Models that use sector-specific capital stocks and costs of adjustment in investment are able to capture important short-run costs due to misallocation of capital. In principle, models with adjustment costs in labor demand could capture additional short-run costs due to labor misallocation as well. It would be most accurate to say that many existing CGE models are not designed for analyzing short-run transitional costs, rather than it being a problem inherent in the methodology. Finally, because CGE models differ considerably from one another in design and parameterization, it is valuable to use multiple models when possible, especially for policies expected to have very large effects on the economy. When EPA uses CGE analysis, it often does use multiple models and it would be very useful to note that in the text.

Finally, the issues of validity and reliability mentioned in other areas of the Advisory are equally relevant to CGE models. We suggest EPA make this point in this chapter and refer readers to the broader discussion of these issues elsewhere.

Question 8: Distributional Analyses

Does Chapter 9: Distributional Analyses: Economic Impact Analyses and Equity Assessment contain an objective and reasonable presentation of the measurement of economic impacts, including approaches suitable to estimate impacts of environmental regulations on the private sector, public sector and households? This discussion includes, for example, the measurement of changes in market prices, profits, facility closure and bankruptcy rates, employment, market structure, innovation and economic growth, regional economies, and foreign trade.

Chapter 9 contains an objective presentation of many of the aspects of economic impact analyses (EIA). It tackles market prices, profits, facility closures, unemployment, market structure, innovation, and growth. Although Chapter 9 contains information on estimating the economic impact of policies, discussing three approaches briefly: Direct Compliance Costs, Partial Equilibrium and Computable General Equilibrium (CGE), it points to Chapter 8 for more details. To make Chapter 9 stand alone, developing brief examples from chapter 8 for both partial and CGE may further the reader's understanding of why these are more effective than the direct compliance costs. Also, augmenting the warning of the complexity of CGE modeling may be worthwhile.

While there is attention to the implementation of CGE models, the discussion of partial equilibrium models basically directs the reader to find supply and demand curves or elasticities, but there are multiple ways of implementing partial equilibrium models. One which would tie this chapter to the benefits chapter is the "production function" approach. More discussion concerning implementation would be valuable.

The *Guidelines* acknowledge that input-output (I-O) models have important conceptual shortcomings as measures of economic benefits and costs. In addition, it might be pointed out that I-O models ignore opportunity cost of resources, implicitly assuming that inputs used in some new activity would otherwise go be idle and have no opportunity cost. For example, I-O analyses frequently use multipliers to calculate jobs "created" due to the direct, indirect and induced effects of an activity. A proper measure of benefits would account for the opportunity costs by subtracting the value of labor in its next best use.

Some other miscellaneous points to consider:

- Linear programming (LP) is more of an optimization method than an economic concept or model.
- There should be some discussion of the marginal cost of public funds as a cost of policies. This may belong in Chapter 8 rather than Chapter 9.

There should be a discussion of the implications of distortions other than taxes for costs, such as imperfect competition and rent seeking public interventions.

Question 9: Measuring Equity Effects

Does this chapter contain a reasonable presentation and set of recommendations on the selection of economic variables and data sources used to measure the equity dimensions identified as potentially relevant to environmental policy analysis?

Data sources for both items are reasonably well addressed in Chapter 9. For information on the former, the U.S Census (household and economic) provides a majority of the data while industry rating agencies provide a deeper understanding on which industries are susceptible as described in the document (9.5.2 - 9.5.4). However, there is some uncertainty in how to obtain information on government entities as only accessing data through "community or state finance agencies" is mentioned (9.5.2.2). Information on assessing how the populations of interest are being affected can be found via various environmental sources pointed out in Section 9.8.4. Overall, the chapter contains all the relevant economic variables necessary in an equity analysis. To support analysts, EPA might consider creation of a website to catalog all of the data sources.

The chapter also provides a reasonable discussion of what the analyst should consider in measuring the distributional aspects of regulations. The main items in assessing equity issues are correctly identifying the populations of concern and accounting for how the populations of interest are being affected. In doing so, it is important to balance data acquisition costs against the value of accuracy.

One limitation we note is that the main distributional issues that are discussed in this chapter relate to the cost side: i) direct compliance expenditures (p. 9-17), ii) indirect costs (taking into account multipliers, GE effects, etc.), and iii) enforcement costs. The bulk of the chapter relates to direct compliance expenditures, and discusses how regulation influences prices, through changes in the composition of industry for example. This focus on the cost side misses many important issues related to environmental justice. EPA should note that there may be just as much interest in considering the distributional effects of benefits of an environmental change. The costs of identifying the distribution of benefits may be much more data intensive and costly than identifying the distribution of costs. Nonetheless, it would seem appropriate for this document to represent the ideal case as one in which the equity and impacts associated with both benefits and costs are considered.

In the context of describing the benefits, costs, or net benefits distribution across populations, it would be useful to describe how the concepts of Lorenz curves and/or Gini coefficients could be used.

Question 10: Economic Literature

Appendix A: Economic Theory was prepared for those readers who wished to have a better understanding of the economic foundations underlying benefit cost analyses. Does Appendix A summarize the relevant literature in an objective and meaningful way? Are there topics that warrant (more) discussion in this appendix that were otherwise missed?

The Appendix provides a thorough and clean discussion of the core economic foundations relevant to benefit-cost analysis with two exceptions. First, a discussion explaining the distinction between stock and flow pollutants should be added. A stock pollutant is an unwanted byproduct of production or consumption that accumulates through time whereas a flow pollutant does not accumulate. Much of the *Guidelines* deals only with a special case where the damage from pollution comes exclusively from the one-period flow of the pollutant and does not consider the general case where the damage comes the accumulated stock of the pollutant. This distinction can be important when undertaking benefit-cost analysis for pollution reduction as the form of the damage function differs. Since greenhouse gases are a prominent and potentially catastrophic stock pollutant, this is an especially important topic for the *Guidelines* to address.

Second, the concept of "user cost" should be defined and explained. User cost relates to forgone future benefits of a resource. That is, exhaustible resources used today will not be available for future use. Benefit-cost analysis related to resource stocks will often need to consider and estimate user costs so its inclusion is important.

Question 11: Omissions

Please identify and enumerate any inconsistencies you may find across chapters and other issues/topics on which we should provide further elaboration. Also, please identify any definitions provided in the new glossary that are inaccurate or that otherwise need revision.

Most of our advice on cross-cutting issues is provided in the Introduction to this Advisory. Below are a few additional ideas that merit consideration.

First and foremost, the Guidelines sorely need case studies and examples to illustrate and make concepts concrete and meaningful.

International trade in market and nonmarket goods is not adequately covered in the *Guidelines*. The discussion of costs, for example, generally assumes a closed economy without international competition. The discussion of policy instruments focuses exclusively on the management of "internal" externalities.

Dynamics are another issue receiving inadequate attention in the *Guidelines*, although dynamic models are discussed in the CGE chapter. Dynamics become relevant to policy analysis, and to estimation of benefits and costs in several contexts. One context is stock pollution problems, climate change being the leading example. Another is when the costs of pollution control or the benefits of pollution reductions have dynamic elements. The costs of pollution control have dynamic elements when there are capital adjustment costs and when there is induced technological change – both features of the "real world." Benefits of pollution reductions have dynamic elements when pollutants are stock pollutants, and when those damaged by pollution have capital adjustment costs in adapting to environmental conditions, and when environmental conditions induce innovations among those who are damaged. Dynamics in these contexts are important in benefit and cost estimation.

Appendix: Compilation of Line by Line Comments from Individual Members

The following comments are suggested edits from individual panelists. As these comments were minor and not considered for full panel deliberation, they are listed separately here for the Agency's consideration.

Page 4-3, Line 13: Drop statement "... does not attempt to detail the relative merits of putting them into practice ...". Report discusses merits of various approaches.

Section 4.1: Divide this section into two parts: (i) Efficient Level of Pollution (MD = MACaggregate) and (ii) Cost-Effective Level of Pollution – minimize cost across sources (MAC1= MAC2= ... = MACn). Each will need a supporting graph and should be integrated by showing aggregate MAC is derived from individual MACs. See Field and Field textbook for dividing the discussion in this way. Also, in discussion of efficient level of pollution be sure to define social welfare using underpinnings of Pareto Optimality. In the discussion of efficient level of pollution note that in the presence of uncertainly, one may prefer to think of the efficient level of pollution as a distribution about E*.

Section 4.2: Divide this section by (i) design standards and (ii) performance standards for clarity. They seem to bump up against each other in the discussion. Be clear about the difference between design standards (technology forcing) and technology based performance standards. Show uniform and technology-based performance standards using cost-effectiveness graph introduced in previous section. Uniform standards are not cost effective but have a low information burden (do not need to know MACs) and technology-based performance standards are cost effective in principle but have a high information burden (need to know MACs).

Page 4-6, Lines 2-4: Definition of Command and Control (CAC) is not quite right. CAC sets requirements on specific firms. Please clarify. Also, consider dropping the terminology CAC. Simply refer to these directly as design and performance standards.

Page 4-6, Lines 28-29: Drop "...firms are not responsive to price signals ..." and "... random events and emergencies ...". Emergency argument for standards is ok but it can be applied in the context of any regulatory approach including market-based approaches.

Page 4-6, Lines 31-32: This sentence is incorrect. Polluters may have face different design or performance standards under CAC regulations.

Section 4.3: When the section on market based regulations is introduced, state why economists tend to prefer these controls: they tend to be least costly, have a low information burden on regulators, and provide incentives for technological advancement. Monitoring and enforcement costs and other administrative costs, of course, can favor direct regulation.

Page 4-8, Coase Box: Even when the conditions mentioned in the opening sentence of the third paragraph of the Coase Box are met, the Coasian solution may not be reached due to asymmetric information and bargaining strategies (ala principle-agent theory) followed by the parties to the transaction. Please qualify the statement accordingly. Also, full information is not a necessary condition for a bargain, even a socially efficient bargain, to take place.

Page 4-9, Line 31: Not sure what is meant by "...when only one permit price exists." When would more exist? Please clarify or drop.

Section 4.3.1.1: Use cost-effectiveness graph to tell the cap & trade story demonstrating its property as a least costly instrument. Also, instead of telling the cap and trade story assuming an efficient level for permit allocations from the start, tell the story that for any aggregate level of emission there exists a cap and trade will be least costly. Then point out that the efficient solution is a special case where the permit allocation is efficient (MD=MAC).

Page 4-11, Lines 23-24: Mention an ambient-based trading scheme directly for dealing with non-uniform mixing (hot spots) and then explain why, due to administrative costs, something intermediate (zones) between emissions based scheme and ambient base scheme maybe efficient.

Section 4.3.2: Expand the discussion of the revenue raising property of the tax and how it can be used to displace other distortionary taxes.

Section 4.3.2: Again, separate cost effectiveness for any given level of emission from efficient (Pigouvian) for special case.

Section 4.3.2: Include some discussion of targeting the tax. Do you target the tax on the pollutant, input, process, or elsewhere? In principle you should place it on damages, but administrative and monitoring costs may suggest targeting elsewhere. Taxing gas is much easier and probably as effective as taxing damages from auto emissions.

Somewhat related to the previous point, please note that policy design is dependent on observable and available information. For example if the policy makers can not observe actual pollution levels but inputs and practices that cause pollution can be observed and there are reasonable estimates on relationship between the input and technology use and the pollution level, then taxes or regulations or fees are based on the imputed pollution levels. Policy makers should be aware of the available information and design policies to best take advantage of the available knowledge. In particular identifying sources of heterogeneity among users and knowing how they affect pollution levels is crucial to policy design. The proliferation of geographic information systems and remote systems to obtain data provide new opportunities for policy design. Studies suggest that there is a significant efficiency gain from policies that adjust to observed heterogeneity relative to uniform policies (Xabadia et-al 2008). Availability of new sources of or means to obtain information may lead to redesign of policies – for example, availability of a technology

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of cheap monitoring of pollution may lead to regulation on taxation based on annual pollution rather than imputed pollution. Policy makers should reassess policy design and implementation as technology progresses. See Xabadia, Angels, Goetz, Renan-Ulrich and Zilberman, David, "The Gains from Differentiated Policies to Control Stock Pollution When Producers are Heterogeneous". American Journal of Agricultural Economics, Vol. 90, No. 4, pp. 1059-1063.

Section 4.3.3: Divide section by (i) subsidy per unit emission and (ii) other subsidies. It more or less falls out that way now, but a clear separation would help.

Page 4-14, Lines 2-4: Drop "However, there may be cases in which a subsidy is more feasible than an emissions tax especially when it is difficult to identify polluters, or when research and development activities relevant to emission abatement would otherwise be under-funded." First part of sentence is handled elsewhere and what does "Underfunded" mean? Is there a market failure here?

Page 4-18, Lines 20-24: Drop this passage. A more meaningful distinction between liability rules and other regulations is that they are ex post regulations usually used in cases of accidents or episodic environmental events, not typical flow pollutant cases.

Section 4.4.2: Mention that information disclosure strategies can allow the market create incentives for pollution control (following Coase) with the victims directly signaling their preferences to firms. But these are most likely to work when there are contractual obligations between polluting firms and affected parties (e.g. consumers/workers) and more difficult to work when they affect third parties (see Tietenberg, "Disclosure Strategies for Pollution Control," Environmental and Resource Economics, April-June 1998, v. 11, iss. 3-4, pp. 587-602. Also it should be mentioned that credibility of information is important. Information disclosure can lead to inefficient outcomes when information is not credible (see Brouhle, K. and M. Khanna, "Information and the Provision of Quality-Differentiated Goods," Economic Inquiry: 45(2): 377-395, April, 2007).

Section 4.4.3: Move this section into the market incentive sections and expand the discussion to include issues of limited assets, activity level incentives, courts costs and so forth. See Segerson (1995) for a nice summary.

Page 4-18, Footnote 54: Another study that shows the types of firms that had incentives to improve environmental performance following negative stock market returns is Khanna, M., W. Quimio, and D. Bojilova, "Toxic Release Information: A Policy Tool for Environmental Protection," *Journal of Environmental Economics and Management*, 36 (3): 243-266, November 1998.

Page 4-19, Line 19: "...information on investment options .." This speaks more to the public goods property of information provision than it does information disclosure. It has not really been mentioned until now and is different than information disclosure. Consider bringing information provision into chapter. There may be a under provision of

information on technology following a public goods argument. See Goulder and Parry (2008).

Section 4.5.3: Weitzman argument. When MAC's are uncertain, and if MD is believed to be constant or flat, then favor a price instrument. If MD is believed to have thresholds or be vertical then favor a quantity instrument. This avoids making costly mistakes. This message does not come across clearly in this section. Also, the "degree of uncertainty" is given as a factor in choosing among policies. This is not technically correct. For example, large uncertainty about emissions is of no policy consequence if the marginal damage cost is constant.

Page 4-22, Line 31: It is incorrect to say that voluntary programs require firms to set goals (also see line 38) or to say that they definitely achieve environmental improvements. Also, it is not accurate to say that most voluntary programs set goals (line 37). They also do not make it simpler to monitor and measure if participants are meeting the goal – most voluntary programs do not require firms to provide emissions data to the EPA (for a review of these issues and comparison of programs see Khanna, M. and D.T. Ramirez, "Effectiveness of Voluntary Approaches: Implications for Climate Change Mitigation," in Voluntary Agreements in Climate Policy, edited by A. Baranzini and P. Thalmann, Edward Elgar Publishers, pp. 31-66, 2004.)

Page 4-23, Footnote 63: The references on voluntary programs are a little outdated. A more recent and updated citation on motivations to participate in different types of voluntary programs, challenges in evaluating their effectiveness and evidence about their effectiveness is Khanna, M. and K. Brouhle, "Effectiveness of Voluntary Environmental Initiatives," Chapter 6 in *Governing the Environment: Interdisciplinary Perspectives*, ed. By M. Delmas and O. Young, Cambridge University Press, Cambridge, U.K. (forthcoming). Khanna, M., "The 33/50 program: Program Design and Effectiveness," in *Reality Check: The Nature and Performance of Voluntary Environmental Programs in the United States, Europe and Japan* edited by R. D. Morgenstern and W. Pizer, RFF Press, Washington DC, 15-42, 2007.

Page 4-24: The box on water quality trading directs people to certain EPA guidance on the design of trading programs. While we think there is merit to these documents, I have reservations about fully endorsing them because there is economically flawed advice about some design elements. This box also misses an opportunity to discuss the importance of economic science to the design of markets. Contemporary water quality markets fail to achieve the promise of trading because of participation and coordination failures that occur in part because of flaws in market design and development. On balance, I recommend dropping the box.

Page 5-2, Line 29: Recommending that the analyst provide "A clear written statement about the *current state of the economy*.." is too broad and may be unnecessary. Instead it is important to clearly specify the current and future state of economic variables that are relevant for the analysis.

Page 5-8, Lines 1-4. The *Guidelines* mention that regulations can lead to innovation (which may not occur in the baseline) which can lead to cost savings. They also mention that there is no statistical evidence supporting this claim of cost savings. Hence they suggest that analysts should avoid assuming differing rates of technological innovation based on regulatory stringency. That last statement (line 4) is incorrect and should be deleted. Instead there should be a brief discussion about the potential for induced innovation due to environmental regulations. Regulations can create incentives for technological innovation that lower the cost of compliance. It should also be recognized that regulations may also discourage innovation in some cases or crowd out other innovations.

Page 6-2, Line 21: NEARLY "any policy"

Page 6-2, Line 37: Can do half-cycle correction, i.e., assume effects occur at mid-year.

Page 6-2, Footnote 73: refers to exponential fn that was apparently deleted from draft

Page 6-4, Line 25 : Note NPV = NFV /(1+r)T.

Page 6-7, Lines 18-20: Text is duplicative

Page 6-10, Footnote 80: Qualify that result requires rate of return > consumption interest rate.

Page 6-15, Section 6.3. Although this section on "intergenerational discounting" is concerned with long time horizon problems, much of the text refers to climate change (e.g., paragraph beginning Page 6-16, Line 6). This is understandable (as that is the most prominent long-horizon problem) but the text could be revised to avoid the impression that it is only about climate change.

Page 7-9, Lines 33-34: The text here mentions possible approaches for valuing morbidity—ex ante and ex post. Please note that studies have also varied in whether they controlled for the opportunity to mitigate the illness (e.g., before or after taking medication).

Page 7-9, Lines 9-10: Recommend not listing fetal loss as a non-fatal health effect – some people would disagree.

Page 7-11, Line 20: Better to say that social costs include private costs (reflected in individual WTP) and external/public costs (e.g., medical care expenses paid by insurance or public sources). The existence of externally paid costs does not mean the individual "understates" own WTP.

Page 7-17, Lines 2-4: I guess this statement is true, but a tighter bound would be one shouldn't include effect for which cost of gathering information exceeds expected improvement in net benefits from choosing a better policy given this information. But I

don't want to make too much of the analytic cost point – seems to me that analytic costs are very small compared with B and C of the major regulations we're mostly considering (e.g., >100 M/yr for many years).

Page 7-19, Lines 15-16: It would help to clarify discussion of when multiple methods are substitutes or complements. In some cases different components will be captured by different methods (e.g., private WTP to reduce health risk, public cost of illness of treating illness), in which case it is appropriate to use both methods and add results (making sure they do not double-count subcomponents). In other cases where different methods provide alternative estimates of the same component, multiple estimates may be useful to triangulate on most accurate value, but should not be added.

Page 7-26, Line 22: Re opportunity cost of time, what if driving to the recreational site is itself enjoyable? After all, in some cases much of the benefit of travel is the journey, not the destination. I'm sure this is discussed in travel cost literature, but I don't follow it.

Page 7-28, Lines 9-11: Strike this sentence. We have no compelling evidence that instantaneous workplace deaths reflect the same tradeoffs that individuals are willing to make over environmental risks.

Page 7-28, line 17: replace "believe" with "assume."

Page 7-28, line 21: the work by Black and Kniesner (2003) uses only risk measures known be fraught with measurement errors (even the "best" data was based on inconsistent reporting of deaths (see Drudi, 1997) and aggregated in a manner that creates serious endogeneity problems (see Leigh, 1995 (JEEM) and Mrozek and Taylor, 2002 (JPAM)). The discussion here could place Black and Kniesner in this context and then look forward to the newer literature.

Page 7-28: The discussion of wage-risk studies needs to be updated with recent results by Kniesner et al. (2007) and Viscusi and Aldy (2007).

Page 7-28: Text on hedonics. What's the point of placing the discussion of the source of workplace risk data where they are now? It's a non-sequitur, and the text does not elaborate on the implications of these sources and of the level of resolution of the workplace risk data.

Page 7-28: Disagree with "Further, while estimates from the hedonic literature have been relatively consistent over the years, questions persist about..." Au contraire, Costa and Kahn (2004) find that in the US the compensating wage differentials required by workers to accept riskier jobs have grown, while workplace risks have declined, resulting in VSLs that have grown over time. Liu and Hammitt (1997) have likewise found that the compensating wage differentials have grown in Taiwan over 16 years, resulting in progressively larger VSLs.

- Page 7-29, line 18 19: The Ashenfelter and Greenstone (2004) study is not a hedonics type of study! It's a revealed preference study of agency choices from which a VSL is inferred.
- Page 7-30, lines 1-10: Would this section be more appropriate in the valuation of mortality/morbidity section?
- Page 7-30: Sources of Risk, first paragraph. It would be useful to cite Eeckhoudt and Hammitt (2001) and also Evans and Smith (2006) who expanded on the notion of competing v. specific risks.
- Page 7-31, Lines 36-38: Please explain the following sentence: "For example, if perceived risks are found to be lower than expert risk estimates, then WTP can be estimated with the lower, perceived risk (Blomquist, 2004)."
- Page 7-35, Line 44: strike "with minimal additional assumptions".
- Page 7-39, Line 29: change "experience, especially..." to read "experience in posted-price markets, especially..."
- Page 7-39, Line 12: John Quiggin prefers to spell his last name "Quiggin" and not "Quiggen."
- Page 7-39, Lines 2-5: Better to say statistical precision than efficiency. As I understand it, efficiency refers to making most use of information available in the data; it is not for comparing different datasets.
- Page 7-39, Lines 38-42: Can you please provide some more recent applications of stated-preference studies using "multi-attribute choice questions?"
- Page 7-40, Lines 37-41: Suggesting that choice questions allow someone to "express support for a program" is counter to the goal of using this method to estimate an actual WTP (not some general notion of "support").
- Pages 7-40 to 7-43: Much of the material feels old and outdated... Assertions about the properties of SP data and the influence of survey design on SP responses are introduced throughout the stated preference section without proper citations to supporting evidence (e.g., page 7-39, lines 27-36, lines 31-33, and lines 34-36).
- Page 7-42, Lines 2-10: The section on Criterion validity over-simplifies the issues. First, for public goods, what is meant by market data? (voluntary contributions markets? political markets?) One should note that theoretically demand revealing mechanisms for public goods are difficult to implement (e.g., Groves-Ledyard), which makes testing the validity of SP surveys for public goods that much more difficult. There have been some studies which compare hypothetical voting on a public good to later actual referenda on

such goods (e.g. Johnston, 2006,) – but this type of criterion test will not generally be available for the policy outcomes being considered by the EPA.

Page 7-42, lines 12-28: For studies that focus on policy-relevant outcomes for the EPA, convergent validity tests will generally not be available (since the goods being considered are not actually "deliverable" by the researcher). Even if similar goods could be delivered, if they are public goods it will be difficult to assure the RP (actual transaction) data are free from biases associated with public good provision. (This comment essentially reiterates the comment above for lines 2-10 on the same page.)

Page 7-43: Survey non-response bias is "created by those who refuse to take the survey" only if their WTP is systematically different from that of those persons who did take the survey. Please make this point clear.

Page 7-44, Line 14, etc.: I don't like the emphasis on doing a new study for each endpoint, since I think that RP & SP studies have so many validity/reliability concerns. On the contrary, I think we are on much stronger grounds having several studies that are relevant from which we can transfer estimates. This may depend on endpoint – for VSL, I want to know what multiple studies say; for some unique ecosystem, I would not care so much about estimated values for effects on other ecosystems.

Page 8-5, Line 44: "In reality, deadweight losses already exist in many if not most markets as a result of taxes, regulations, and other distortions" But presumably, in many cases the regulation will have the goal of correcting existing distortions, such as external costs of pollution. The term "deadweight loss" here is not really a loss if you are considering policies designed to correct externalities. Although the report recognizes that benefits of pollution reduction need to be considered, the term "loss" is not really appropriate here. This is more an issue of terminology, rather than substance.

Section 8.1.1: One of the down sides of partial equilibrium approaches is the possibility of "double counting" impacts. To this end, a clear warning or explanation of doubling counting should be included in the discussion in chapter 9 or chapter 8. Double counting occurs if the outputs from firms operating upstream and downstream are both impacted by the new policy and the impacts are considered separately. The impact on the downstream firm is typically passed on to the upstream firm. For a simple example, consider a fuel policy affecting both a delivery business and a local production business. If one of the local business inputs comes from the delivery business and the policies impact on the local business through this input is including in the partial equilibrium adjustment for the local business, any partial equilibrium analysis for the delivery business should account for this. This warning is especially of interest because the apparent interest in CGE analysis may lead an analyst to estimate multiple partial equilibrium models in place of a CGE due to their relative difficulty.

Section 8.1.3: I wouldn't use the term "economic impacts" since that term generally refers to Economic Impact Analysis, so the term might be incorrectly interpreted. Why not "economic effects".

Section 8.2.1: Alternative Concepts of Cost. The discussion in this section is confusing. If I understand it correctly, these are not alternative concepts of costs, but rather are categories of cost. If properly defined, these categories are simply decompositions of social cost, not "alternative concepts". Does this Section intend to indicate that, for efficiency purposes, only total social costs matter, but decompositions of social cost could provide information on the incidence of costs or the distributional consequences? EPA either needs to explain how these categories are useful, or if they are not useful the discussion could simply be dropped.

Section 8.3.2.1: The report should be more consistent in differentiating between benefits and costs. For example, this section refers to things like "irreversible environmental impacts" as a cost. While it is true that there is no true distinction between costs and negative benefits (e.g., irreversible environmental impacts), the report has separate sections on costs and benefits, and the discussion should be kept consistent by including environmental values in the benefits section.

Section 8.4.4: Input-Output analysis doesn't really belong in this section, since it does not provide a well defined measure of economic costs. We recommend that the discussion be moved to Chapter 9 given its close connection to Economic Impact Analysis and distribution across sectors. Note that Input-Output Analysis does not provide a measure of economic costs and benefits, but output from an I-O analysis could provide some information on how economic effects are distributed across sectors of the economy.

Section 8.2.3. Shouldn't this Section refer to "Distribution of Costs" rather than "Distributional Costs"

Page. 9-1. Footnote 179—avoiding double-counting likely needs more discussion and an example to illuminate the issue.

Page 9-7 and Table 2: Data sources for profiles I would like to add The Thomas Registry is another data source. The Thomas Register, which dates back to 1906, is used primarily by purchasing agents. Lavin [1992] states that the Thomas Register is the best example of a directory which provides information on manufacturers by focusing on products. According to Lavin, "The Thomas Register is a comprehensive, detailed guide to the full range of products manufactured in the United States. Covering only manufacturing companies, it strives for a complete representation within that scope." The EPA should also see the many other types of sources of business information discussed in Lavin, M. R., 1992, Business Information: How to Find It, How to Use It, 2nd ed. (Oryx Press, Phoenix).

Page 9-9, Line 15. They basically punt on pass-through. Perhaps more direction on what to do when basic elasticities are not available.

Page 9-9, Lines 41-42. Is this a cost or benefit? I see it as a net benefit that should be estimated somehow.

Page 9-9, Footnote 192: This then leads to the producers of equipment to dig out the coal being hurt. Be clear about how far down the chain we go.

Page 9-12, Lines 20-22: Regional analysis. Lacks a thorough discussion of regional economies and trade. In this way the document can update FN 204 by including work of Copeland and Taylor and Greenstone.

Page 9-16, Lines 10-12: Another indicator that could be considered at the community level is the foreclosure rate.

Page 9-18, Lines 1-8: This gets us back to the proper counterfactual. In this example they merely discuss the direct cost of the regulation without recognizing that these expenditures have other benefits and costs. For example, they confer tax breaks (complying with regulations is a deductible expense) and that the new capital is more productive than old capital. But a key consideration is whether, and to what extent, the displacement of investment leads this new capital to be less productive than innovation that it displaced.

Page 9-18 - 9-20: Some mention should concern temporal aspects of benefits and costs. For example, the entirety of Ch. 9 contains sections on equity issues for an analysis to consider. In addition to this, a discussion of household movement (Tiebout sorting) may be of interest to account for the long-term equitable distribution. That is, although there may be short run benefits for socially or economically disadvantaged populations, they may not hold in the long run. If these households are not home owners, they may be left out of the gain in benefits if market forces result in disadvantage populations moving because the gains remain attached to home or land and therefore the owner.

Page 9-23: Textbox "2" should be "9.2".

Page 9-26: Extra period in box 9.3.

Page 9-29: What is the definition of poor? What about gender? This seems to be a relatively ad hoc list of equity factors, are there other identifying characteristics that might be relevant? What about intergenerational equity?

Page B-4, Footnote 293: Sunstein (1997) and Hammitt and Liu (2004) are more recent citations.

Page B-7, Footnote 309: Adjustments in the VSL for population characteristics "does imply" (not "may imply") support for variation in protection across the population.

Page A-2, line 4: change "y" to "P" and "x" to "Qd" to be consistent with Figure A.1.

Page A-2, line 19: insert language so sentence reads "The total WTP is equal to the SUM OF THE marginal WTP for each unit up to Q4"

Figure A.3: "P" on the vertical axis needs a "m" subscript to be consistent with the text.

Page A-8, line 7: Change sentence to read: "Benefit-cost analysis can also be SEEN as a type of..."

Page A-8, line 8: We suggest striking "that economists strive to avoid" from the sentence.

Figure A.6: The demand curve could be labeled in the figure directly (especially given there is no title for the figure).

Page A-12, line 32: Change "correct monetary measures of utility change" to read "exact monetary measures of utility change" to be consistent with standard language found in the literature.

Page A-15, line 12: Strike "However," -- it is out of place given the preceding sentence.

Figure A.10: Consider changing the title on the horizontal axis from "Regulation" to "Pollution Abatement" or something similar.

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Office of the Secretary of Transportation

1200 New Jersey Avenue, SE Washington, DC 20590

MEMORANDUM TO:

SECRETARIAL OFFICERS MODAL ADMINISTRATORS

From:

Polly Trottenberg

Under Secretary for Policy

x6-4540

Robert S. Rivkin General Counsel

x6-4702

Subject:

Guidance on Treatment of the Economic Value of a Statistical Life in

U.S. Department of Transportation Analyses

Departmental guidance on valuing reduction of fatalities and injuries by regulations or investments has been published periodically by this office since 1993. We issued a thorough revision of our guidance in 2008 and have issued annual updates to adjust for changes in prices and real incomes since then. Our most recent update, dated July 29, 2011, stated that a new review of the technical literature would be conducted to inform the next publication. The conclusions of that review are incorporated in this guidance.

Empirical studies published in recent years indicate a VSL of \$9.1 million in current dollars for analyses using a base year of 2012. We also find that an income elasticity of 1.0 should be used to project VSL to future years. Based on wage forecasts from the Congressional Budget Office, we estimate that there will be an expected 1.07 percent annual growth rate in median real wages over the next 30 years (2013-2043). These estimates imply that VSL in future years should be estimated to grow by 1.07 percent per year before discounting to present value.

This guidance also includes a table of the relative values of preventing injuries of varied severity, unchanged since the 2011 guidance. We also prescribe a sensitivity analysis of the effects of using alternative VSL values. Instead of treating alternative values in terms of a probability distribution, analysts should apply only a test of low and high alternative values of \$5.2 million and \$12.9 million.

This guidance and other relevant documents will be posted on the Reports page of the Office of Transportation Policy website, http://www.dot.gov/policy, and on the General Counsel's regulatory information website, http://www.dot.gov/regulations. Questions should be addressed to Jack Wells, (202) 366-9224 or jack.wells@dot.gov.

cc: Regulations officers and liaison officers

Revised Departmental Guidance 2013:

Treatment of the Value of Preventing Fatalities and Injuries in Preparing Economic Analyses

On the basis of the best available evidence, this guidance identifies \$9.1 million as the value of a statistical life to be used for Department of Transportation analyses assessing the benefits of preventing fatalities and using a base year of 2012. It also establishes policies for projecting future values and for assigning comparable values to prevention of injuries.

Background

Prevention of injury, illness, and loss of life is a significant factor in many private economic decisions, including job choices and consumer product purchases. When government makes direct investments or controls external market impacts by regulation, it also pursues these benefits, often while also imposing costs on society. The Office of the Secretary of Transportation and other DOT administrations are required by Executive Order 13563, Executive Order 12866, Executive Order 12893, OMB Circular A-4, and DOT Order 2100.5 to evaluate in monetary terms the costs and benefits of their regulations, investments, and administrative actions, in order to demonstrate the faithful execution of their responsibilities to the public. Since 1993, the Office of the Secretary of Transportation has periodically reviewed the published research on the value of safety and updated guidance for all administrations. Our previous guidance, issued on July 29, 2011, stated that a new review of the literature (our first since 2008) would be conducted to inform the next publication. The conclusions of that review are incorporated in this guidance.

The benefit of preventing a fatality is measured by what is conventionally called the Value of a Statistical Life (VSL), defined as the additional cost that individuals would be willing to bear for improvements in safety (that is, reductions in risks) that, in the aggregate, reduce the expected number of fatalities by one. This conventional terminology has often provoked misunderstanding on the part of both the public and decision-makers. What is involved is not the valuation of life as such, but the valuation of reductions in risks. While new terms have been proposed to avoid misunderstanding, we will maintain the common usage of the research literature and OMB Circular A-4 in referring to VSL.

Most regulatory actions involve the reduction of risks of low probability (as in, for example, a one-in-10,000 annual chance of dying in an automobile crash). For these low-probability risks, we shall assume that the willingness to pay to avoid the risk of a fatal injury increases proportionately with growing risk. That is, when an individual is willing to pay \$1,000 to reduce the annual risk of death by one in 10,000, she is said to have a VSL of \$10 million. The assumption of a linear relationship between risk and willingness to pay therefore implies that she would be willing to pay \$2,000 to reduce risk by two in 10,000 or \$5,000 to reduce risk by five in 10,000. The assumption of a linear relationship between risk and willingness to pay (WTP) breaks down when the annual WTP becomes a substantial portion of annual income, so the assumption of a constant VSL is not appropriate for substantially larger risks.

When first applied to benefit-cost analysis in the 1960s and 1970s, the value of saving a life was measured by the potential victim's expected earnings, measuring the additional product society might have lost. These lost earnings were widely believed to understate the real costs of loss of life, because the value that we place on the continued life of our family and friends is not based entirely, or even principally, on their earning capacity. In recent decades, studies based on estimates of individuals' willingness to pay for improved safety have become widespread, and offer a way of measuring the value of reduced risk in a more comprehensive way. These estimates of the individual's value of safety are then treated as the ratio of the individual marginal utility of safety to the marginal utility of wealth. These estimates of the individual values of changes in safety can then

be aggregated to produce estimates of social benefits of changes in safety, which can then be compared with the costs of these changes.

Studies estimating the willingness to pay for safety fall into two categories. Some analyze subjects' responses in real markets, and are referred to as revealed preference (RP) studies, while others analyze subjects' responses in hypothetical markets, and are described as stated preference (SP) studies. Revealed preference studies in turn can be divided into studies based on consumer purchase decisions and studies based on employment decisions (usually referred to as hedonic wage studies). Even in revealed preference studies, safety is not purchased directly, so the value that consumers place upon it cannot be measured directly. Instead, the value of safety can be inferred from market decisions that people make in which safety is one factor in their decisions. In the case of consumer purchase decisions, since goods and services usually display multiple attributes, and are purchased for a variety of reasons, there is no guarantee that safety will be the conclusive factor in any purchasing decision (even products like bicycle helmets, which are purchased primarily for safety, also vary in style, comfort, and durability). Similarly, in employment decisions, safety is one of many considerations in the decision of which job offer to accept. Statistical techniques must therefore be used to identify the relative influence of price (or wage), safety, and other qualitative characteristics of the product or job on the consumer's or worker's decision on which product to buy or which job to accept.

An additional complication in RP studies is that, even if the real risks confronted by individuals can be estimated accurately by the analyst, the consumer or employee may not estimate these risks accurately. It is possible for individuals, through lack of relevant information or limited ability to analyze risks, to assign an excessively low or high probability to fatal risks. Alternatively, detailed familiarity with the hazards they face and their own skills may allow individuals to form more accurate estimates of risk at, for example, a particular job-site than those derived by researchers, which inevitably are based on more aggregate data.

In the SP approach, market alternatives incorporating hypothetical risks are presented to test subjects, who respond with what they believe would be their choices. Answers to hypothetical questions may provide helpful information, but they remain hypothetical. Although great pains are usually taken to communicate probabilities and measure the subjects' understanding, there is no assurance that individuals' predictions of their own behavior would be observed in practice. Against this weakness, the SP method can evaluate many more alternatives than those for which market data are available, and it can guarantee that risks are described objectively to subjects. With indefinitely large potential variations in cost and risk and no uncontrolled variation in any other dimension, some of the objections to RP models are obviated. Despite procedural safeguards, however, SP studies have not proven consistently successful in estimating measures of WTP that increase proportionally with greater risks.

RP studies involving decisions to buy and/or use various consumer products have focused on decisions such as buying cars with better safety equipment, wearing seat belts or helmets, or buying and installing smoke detectors. These studies often lack a continuum of price-risk opportunities, so that the price paid for a safety feature (such as a bicycle helmet) does not necessarily represent the value that the consumer places on the improvement in safety that the helmet provides. In the case of decisions to use a product (like a seatbelt) rather than to buy the product, the "price" paid by the consumer must be inferred from the amount of time and degree of inconvenience involved in using the product, rather than the directly observable price of buying the product. The necessity of making these inferences introduces possible sources of error. Studies of purchases of automobiles probably are less subject to these problems than studies of other consumer decisions, because the price of the safety equipment is directly observable, and there are usually a variety of more or less expensive safety features that provide more of a range of price-risk trade-offs for consumers to make.

While there are many examples of SP studies and RP studies involving consumer product purchases, the most widely cited body of research comprises hedonic wage studies, which estimate the wage differential that

employers must pay workers to accept riskier jobs, taking other factors into account. Besides the problem of identifying and quantifying these factors, researchers must have a reliable source of data on fatality and injury risks and also assume that workers' psychological risk assessment conforms to the objective data. The accuracy of hedonic wage studies has improved over the last decade with the availability of more complete data from the Bureau of Labor Statistics' (BLS) Census of Fatal Occupational Injuries (CFOI), supported by advances in econometric modeling, including the use of panel data from the Panel Study of Income Dynamics (PSID). The CFOI data are, first of all, a complete census of occupational fatalities, rather than a sample, so they allow more robust statistical estimation. Second, they classify occupational fatalities by both industry and occupation, allowing variations in fatalities across both dimensions to be compared with corresponding variations in wage rates. Some of the new studies use panel data to analyze the behavior of workers who switch from one job to another, where the analysis can safely assume that any trade-off between wage levels and risk reflects the preferences of a single individual, and not differences in preferences among individuals.

VSL estimates are based on studies of groups of individuals that are covered by the study, but those VSL estimates are then applied to other groups of individuals who were not the subjects of the original studies. This process is called benefit transfer. One issue that has arisen in studies of VSL is whether this benefit transfer process should take place broadly over the general population of people that are affected by a rulemaking, or whether VSL should be estimated for particular subgroups, such as workers in particular industries, and people of particular ages, races, and genders. Advances in data and econometric techniques have allowed specialized estimates of VSL for these population subgroups. Safety regulations issued by the Department of Transportation typically affect a broad cross-section of people, rather than more narrowly defined subgroups. Partly because of that, and partly for policy reasons, we do not consider variations in VSL among different population groups (except to take into account the effect on VSL of rising real income over time).

Principles and policies of DOT guidance

This guidance for the conduct of Department of Transportation analyses is a synthesis of empirical estimates, practical adaptations, and social policies. We continue to explore new empirical literature as it appears and to give further consideration to the policy resolutions embodied in this guidance. Although our approach is unchanged from previous guidance, the numbers and their sources are new, consistent with OMB guidance in Circular A-4 and other sources, and with the use of the best available evidence. The methods we adopt are:

- 1. Prevention of an expected fatality is assigned a single, nationwide value in each year, regardless of the age, income, or other distinct characteristics of the affected population, the mode of travel, or the nature of the risk. When Departmental actions have distinct impacts on infants, disabled passengers, or the elderly, no adjustment to VSL should be made, but analysts should call the attention of decision-makers to the special character of the beneficiaries.
- 2. In preparing this guidance, we have adjusted the VSL from the year of the source data to the year before the guidance is issued, based on two factors: growth in median real income and monetary inflation, both measured to the last full year before the date of the guidance.
- 3. The value to be used by all DOT administrations will be published annually by the Office of the Secretary of Transportation.
- 4. Analysts should project VSL from the base year to each future year based on expected growth in real income, according to the formula prescribed on page 8 of this guidance. Analysts should not project future changes in VSL based on expected changes in price levels.

5. Alternative high and low benefit estimates should be prepared, using a range of VSLs prescribed on page 10 of this guidance.

In Circular A-4 (2003), the Office of Management and Budget endorsed VSL values between \$1 million and \$10 million, drawing on two recently completed VSL meta-analyses. ¹ In 2012 dollars, these values would be between \$1.24 million and \$12.4 million. The basis for the previous DOT guidance, adopted on February 5, 2008, comprised five studies, four of which were meta-analyses that synthesized many primary studies, identifying their sources of variation and estimating the most likely common parameters. These studies were written by Ted R. Miller; ² Ikuho Kochi, Bryan Hubbell, and Randall Kramer; ³ W. Kip Viscusi; ⁴ Janusz R. Mrozek and Laura O. Taylor; ⁵ and W. Kip Viscusi and Joseph Aldy. ⁶ They narrowed VSL estimates to the \$2 million to \$7 million range in dollar values of the original data, between 1995 and 2000 (about \$3 million to \$9 million at current prices). Miller and Viscusi and Aldy also estimated income elasticities for VSL (the percent increase in VSL per one percent increase in income). Miller's estimates were close to 1.0, while Viscusi and Aldy estimated the elasticity to be between 0.5 and 0.6. DOT used the Viscusi and Aldy elasticity estimate (averaged to 0.55), along with the Wages and Salaries component of the Employer Cost for Employee Compensation, as well as price levels represented by the Consumer Price Index, to project these estimates to a 2007 VSL estimate of \$5.8 million.

Since these studies were published, the credibility of these meta-analyses has been qualified by recognition of weaknesses in the data used by the earlier primary studies whose results are synthesized in the meta-analyses. We now believe that the most recent primary research, using improved data (particularly the CFOI data discussed above) and specifications, provides more reliable results. This conclusion is based in part on the advice of a panel of expert economists that we convened to advise us on this issue. The panel consisted of Maureen Cropper (University of Maryland), Alan Krupnick (Resources for the Future), Al McGartland (Environmental Protection Agency), Lisa Robinson (independent consultant), and W. Kip Viscusi (Vanderbilt University). The Panel unanimously concluded that we should base our guidance only on hedonic wage studies completed within the past 10 years that made use of the CFOI database and used appropriate econometric techniques.

A White Paper prepared for the U.S. Environmental Protection Agency (EPA) in 2010 identifies eight hedonic wage studies using the CFOI data; we have also identified seven additional studies, including five published since the EPA White Paper was issued (see Table 1). Some of these studies focus on estimating VSL values for narrowly defined economic, demographic, or occupational categories, or use inappropriate econometric techniques, resulting in implausibly high VSL estimates. We have therefore focused on nine studies that we

¹ Viscusi, W. K. and J.E. Aldy (2003). "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World." *Journal of Risk and Uncertainty*, 27(1): 5-76; and Mrozek, J.R. and L. O. Taylor (2002). "What Determines the Value of a Life? A Meta-Analysis." *Journal of Policy Analysis and Management*. 21(2).

²Miller, T. R. (2000). "Variations between Countries in Values of Statistical Life." *Journal of Transport Economics and Policy*. 34(2): 169-188. http://www.bath.ac.uk/e-journals/jtep/pdf/Volume_34_Part_2_169-188.pdf

³Kochi, I., B. Hubbell, and R. Kramer (2006). "An Empirical Bayes Approach to Combining and Comparing Estimates of the Value of a Statistical Life for Environmental Policy Analysis." *Environmental and Resource Economics*. 34(3): 385-406.

⁴Viscusi, W. K. (2004). "The Value of Life: Estimates with Risks by Occupation and Industry." Economic Inquiry. 42(1): 29-48.

⁵ Mrozek, J. R., and L. O. Taylor (2002). "What Determines the Value of Life? A Meta-Analysis." *Journal of Policy Analysis and Management.* 21(2).

⁶ Viscusi, W. K. and J. E. Aldy (2003). "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World." *Journal of Risk and Uncertainty*. 27(1): 5-76.

⁷ U.S. Environmental Protection Agency (2010), Valuing Mortality Risk Reductions for Environmental Policy: A White Paper (Review Draft). Prepared by the National Center for Environmental Economics for consultation with the Science Advisory Board – Environmental Economics Advisory Committee.

think are useful for informing an appropriate estimate of VSL. There is broad agreement among researchers that these newer hedonic wage studies provide an improved basis for policy-making.⁸

The 15 hedonic wage studies we have identified that make use of the CFOI database to estimate VSL are listed in Table 1. Several of these studies focus on estimating how VSL varies for different categories of people, such as males and females, older workers and younger workers, blacks and whites, mmigrants and non-immigrants, and smokers and non-smokers, as well as for different types of fatality risks. Some of these studies do not estimate an overall ("full-sample") VSL, instead estimating VSL values only for specific categories of people. Some of the studies, as the authors themselves sometimes acknowledge, arrive at implausibly high values of VSL, because of econometric specifications which appear to bias the results, or because of a focus on a narrowly-defined occupational group. Moreover, these papers generally offer multiple model specifications, and it is often not clear (even to the authors) which specification most accurately represents the actual VSL. We have generally chosen the specification that the author seems to believe is best. In cases where the author does not express a clear preference, we have had to average estimates based on alternative models within the paper to get a representative estimate for the paper as a whole.

Table 1: VSL Studies Using CFOI Database

(VSLs in millions of dollars)

	<u>Study</u>	Year of Study \$	VSL in Study- Year \$	<u>VSL in</u> 2012\$	Comments
Ĩ.	Viscusi (2003) *	1997	\$14.185M	\$21.65M	Implausibly high; industry- only risk measure
2.	Leeth and Ruser (2003) *	2002	\$7.04M	\$8.90M	Occupation-only risk measure
3.	Viscusi (2004)	1997	\$4.7M	\$7.17M	Industry/occupation risk measure
4.	Kniesner and Viscusi (2005)	1997	\$4.74M	\$7.23M	Industry/occupation risk measure
5.	Kniesner <i>et al.</i> (2006) *	1997	\$23.70M	\$36.17M	Implausibly high; industry/occupation risk measure

⁸A current survey of theoretical and empirical research on VSL may be found in: Cropper, M., J.K. Hammitt, and L.A. Robinson (2011). "Valuing Mortality Risk Reductions: Progress and Challenges." *Annual Review of Resource Economics.* 3: 313-336. http://www.annualreviews.org/doi/abs/10.1146/annurev.resource.012809.103949

⁹ Leeth, J.D. and J. Ruser (2003). "Compensating Wage Differentials for Fatal and Nonfatal Injury Risks by Gender and Race." *Journal of Risk and Uncertainty*, 27(3): 257-277.

¹⁰ Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2006). "Life-Cycle Consumption and the Age-Adjusted Value of Life." Contributions to Economic Analysis and Policy. 5(1): 1-34; Viscusi, W.K. and J.E. Aldy (2007). "Labor Market Estimates of the Senior Discount for the Value of Statistical Life." Journal of Environmental Economics and Management. 53: 377-392; Aldy, J.E. and W.K. Viscusi (2008). "Adjusting the Value of a Statistical Life for Age and Cohort Effects." Review of Economics and Statistics. 90(3): 573-581; and Evans, M.F. and G. Schaur (2010). "A Quantile Estimation Approach to Identify Income and Age Variation in the Value of a Statistical Life." Journal of Environmental Economics and Management. 59: 260-270.

¹¹ Viscusi, W.K. (2003). "Racial Differences in Labor Market Values of a Statistical Life." *Journal of Risk and Uncertainty*. 27(3): 239-256, and Leeth, J.D. and J. Ruser (2003), op. cit.

¹² Hersch, J. and W.K. Viscusi (2010). "Immigrant Status and the Value of Statistical Life." *Journal of Human Resources*. 45(3): 749-771.

¹³ Viscusi, W.K. and J. Hersch (2008). "The Mortality Cost to Smokers." Journal of Health Economics. 27: 943-958.

¹⁴ Scotton, C.R. and L.O. Taylor. "Valuing Risk Reductions: Incorporating Risk Heterogeneity into a Revealed Preference Framework." *Resource and Energy Economics*. 33 and Kochi, I and L.O. Taylor (2011). "Risk Heterogeneity and the Value of Reducing Fatal Risks: Further Market-Based Evidence." *Journal of Benefit-Cost Analysis*. 2(3): 381-397.

6.	Viscusi and Aldy (2007) *	2000			Industry-only risk measure; no full-sample VSL estimate
7.	Aldy and Viscusi (2008) *	2000	, , , ,	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Industry-only risk measure, no full-sample VSL estimate
8.	Evans and Smith (2008)	2000	\$9.6M	\$12.84M	Industry-only risk measure
9.	Viscusi and Hersch (2008)	2000	\$7.37M	\$9.86M	Industry-only risk measure
10.	Evans and Schaur (2010)	1998	\$6.7M	\$9.85M	Industry-only risk measure
11.	Hersch and Viscusi (2010)	2003	\$6.8M	\$8.43M	Industry/occupation risk measure
12.	Kniesner et al. (2010)	2001	\$7.55M	\$9.76M	Industry/occupation risk measure
13.	Kochi and Taylor (2011)*	2004			VSL estimated only for occu- pational drivers
14.	Scotton and Taylor (2011)	1997	\$5.27M	\$8.04M	Industry/occupation risk measure; VSL is mean of estimates from three preferred specifications
15.	Kniesner et al. (2012)	2001	\$4M - \$10M	\$5.17M - \$12.93M	Industry/occupation risk measure; mean VSL estimate is \$9.05M

^{*} Studies shown in grayed-out rows were not used in determining the VSL Guidance value.

We found that nine of these studies provided usable estimates of VSL for a broad cross-section of the population. We excluded Viscusi (2003) and Kniesner *et al.* (2006) on the grounds that their estimates of VSL were implausibly high (Viscusi acknowledges that the estimated VSLs in his study are very high). We excluded Leeth and Ruser (2003) because it used only variations in occupation for estimating variation in risk (the occupational classifications are generally regarded as less accurate than the industry classifications). We excluded Viscusi and Aldy (2007) and Aldy and Viscusi (2008) because they did not estimate overall "full-sample" VSLs (they focused instead on estimating VSLs for various subgroups). We excluded Kochi and Taylor (2011) because it estimated VSL only for a narrow occupational group (occupational drivers). For Scotton and Taylor (2011) and Kniesner *et al.* (2012) we calculated average values for VSL from what appeared to be the preferred model specifications. For this guidance, we adopt the average of the VSLs estimated in the remaining nine studies, updated to 2012 dollars (based both on changes in the price level and changes in real incomes from the year for which the VSL was originally estimated). This average is \$9.14 million, which we round to \$9.1 million for purposes of this guidance.

Our current guidance specifies that our VSL guidance will be updated each year, to take into account both the increase in the price level and the increase in real incomes. The VSL literature is generally in agreement that VSL increases with real incomes, but the exact rate at which it does so is subject to some debate. In our

¹⁵ In addition to Viscusi (2004) [cited in footnote 4], Viscusi and Hersch (2008) [cited in footnote 13], Evans and Schaur (2010) [cited in footnote 10], Hersch and Viscusi (2010) [cited in footnote 12], and Scotton and Taylor (2011) [cited in footnote 14], these include Kniesner, T.J. and W.K. Viscusi (2005). "Value of a Statistical Life: Relative Position vs. Relative Age." AEA Papers and Proceedings. 95(2): 142-146; Evans, M.F. and V.K. Smith (2008). "Complementarity and the Measurement of Individual Risk Tradeoffs: Accounting for Quantity and Quality of Life Effects." National Bureau of Economic Research Working Paper 13722; Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2010). "Policy Relevant Heterogeneity in the Value of Statistical Life: New Evidence from Panel Data Quantile Regressions." Journal of Risk and Uncertainty. 40: 15-31; and Kniesner, T.J., W.K. Viscusi, C. Woock, and J.P. Ziliak (2012). "The Value of a Statistical; Life: Evidence from Panel Data." Review of Economics and Statistics. 94(1): 74-87.

current guidance, we cite research by Viscusi and Aldy (2003) that estimated the elasticity of VSL with respect to increases in real income as being between 0.5 and 0.6 (i.e., a one-percent increase in real income results in an increase in VSL of 0.5 to 0.6 percent). We accordingly have increased VSL by 0.55 percent for every one-percent increase in real income. More recent research by Kniesner, Viscusi, and Ziliak (2010) has derived more refined income elasticity estimates ranging from 2.24 at low incomes to 1.23 at high incomes, with an overall figure of 1.44. An alternative specification yielded an overall elasticity of 1.32. Similarly, Costa and Kahn (2004) estimated the income-elasticity of VSL to be between 1.5 and 1.6. These empirical results are consistent with theoretical arguments suggesting that the income-elasticity of VSL should be greater than 1.0. 18

In view of the large increase in the income elasticity of VSL that would be suggested by these empirical results, and because the literature seems somewhat unsettled, we will increase our suggested income-elasticity figure only to 1.0. While this figure is lower than the elasticity estimates of Kniesner *et al.* and Costa and Kahn, it is higher than that of Viscusi and Aldy, the basis for our previous guidance. It is difficult to state with confidence whether a cross-sectional income elasticity (such as those estimated in these empirical analyses), representing the difference in sensitivity to fatality risks between low-income and high-income workers in a given population, corresponds to a longitudinal elasticity, representing the way in which VSL is affected by growth in income over time for an overall population. Consequently, we adopt this more moderate figure, pending more comprehensive documentation.

The index we use to measure real income growth as it affects VSL is the Median Usual Weekly Earnings (MUWE), in constant (1982-84) dollars, derived by BLS from the Current Population Survey (Series LEU0252881600 – not seasonally adjusted). This series is more appropriate than the Wages and Salaries component of the Employment Cost Index (ECI), which we used previously, because the ECI applies fixed weights to employment categories, while the weekly earnings series uses a median employment cost for wage and salary workers over the age of 16. A median value is preferred because it should better reflect the factors influencing a typical traveler affected by DOT actions (very high incomes would cause an increase in the mean, but not affect the median). In contrast to a median, an average value over all income levels might be unduly sensitive to factors that are less prevalent among actual travelers. Similarly, we do not take into account changes in non-wage income, on the grounds that this non-wage income is not likely to be significant for the average person affected by our rules. The MUWE has been virtually unchanged for the past decade, so this has very little effect on the VSL adjustment over the past ten years. However, it is likely to be more significant in the future.

We have chosen the Consumer Price Index (CPI-U) as a price index that similarly is representative of changes in the value of money that would be considered by a typical worker making decisions corresponding to his income level. This index grew from 2002 to 2012 by 27.62 percent, raising estimates of VSL in 2002 dollars by over 27 percent over ten years.

In 2011, we adopted a procedure for estimating VSL in each future year as it would respond to expected growth in real income levels. Logical consistency required that higher incomes in the future would influence projected VSLs, just as they affect the current year's baseline. The procedure we now specify uses the projected rate of

¹⁶ Kniesner, T.J., W.K. Viscusi, and J.P. Ziliak (2010). "Policy Relevant Heterogeneity in the Value of Statistical Life: New Evidence from Panel Data Quantile Regressions." *Journal of Risk and Uncertainty.* 40(1):15–31.

¹⁷ Costa, D.L. and M.E. Kahn (2004). "Changes in the Value of Life, 1940-1980." *Journal of Risk and Uncertainty.* 29(2): 159-180. ¹⁸ Eeckhoudt, L.R. and J.K. Hammitt (2001). "Background Risks and the Value of a Statistical Life." *Journal of Risk and Uncertainty.* 23(3): 261-279; Kaplow, L. (2005). "The Value of a Statistical Life and the Coefficient of Relative Risk Aversion." *Journal of Risk and Uncertainty,* 31(1); Murphy, K.M. and R.H. Topel (2006). "The Value of Health and Longevity." *Journal of Political Economy.* 114(5): 871-904; and Hammitt, J.K. and L.A. Robinson (2011). "The Income Elasticity of the Value per Statistical Life: Transferring Estimates between High and Low Income Populations." *Journal of Benefit-Cost Analysis.* 2(1): 1-27.

growth of the Real Median Wage for Workers Covered by Social Security, estimated by the Congressional Budget Office (CBO). While the growth rate forecast fluctuates significantly over the next decade in response to incentives in the Affordable Care Act to receive wage compensation versus health insurance benefits, we believe that it is reasonable to use a long-term average growth rate to estimate changes in future VSL. We have calculated the average projected growth rate in the real median wage, based on the CBO data over the next 30 years, to be 1.07 percent per year. With an income elasticity of 1.0, the base-year VSL should thus be increased by 1.07 percent per year to estimate VSL for any future year (in base-year dollars), before discounting to present value. 20

For future years, the formula for calculating future values of VSL is therefore:

 $VSL_{2012+N} = VSL_{2012} \times 1.0107^{N}$

where VSL_{2012+N} is the VSL value N years after 2012

and VSL₂₀₁₂ is the VSL value in 2012 (i.e., \$9.1 million).

When conducting sensitivity analyses using alternative VSL values (see page 10), analysts should use those alternative VSL values in place of the \$9.1 million value used here. We emphasize that future VSL values should be adjusted only for changes in real wages, not for changes in price levels. For analysts using base years prior to 2012, the new VSL for 2011 (adjusted for changes in real income and prices) is \$8.98 million in 2011 dollars. For 2010, this value is \$8.86 million in 2010 dollars.

Value of Preventing Injuries

Nonfatal injuries are far more common than fatalities and vary widely in severity, as well as probability. In principle, the resulting losses in quality of life, including both pain and suffering and reduced income, should be estimated by potential victims' WTP for personal safety. While estimates of WTP to avoid injury are available, often as part of a broader analysis of factors influencing VSL, these estimates are generally only available for an average injury resulting in a lost workday, and not for a range of injuries varying in severity. Because detailed WTP estimates covering the entire range of potential disabilities are unobtainable, we use an alternative standardized method to interpolate values of expected outcomes, scaled in proportion to VSL. Each type of accidental injury is rated (in terms of severity and duration) on a scale of quality-adjusted life years (QALYs), in comparison with the alternative of perfect health. These scores are grouped, according to the Abbreviated Injury Scale (AIS), yielding coefficients that can be applied to VSL to assign each injury class a value corresponding to a fraction of a fatality.

In our previous guidance, the values of preventing injuries were updated by new estimates from a study by Spicer and Miller.²¹ The measure adopted was the quality-adjusted percentage of remaining life lost for median

¹⁹ The projected growth of the mean real wage is reported by CBO in its 2012 Long-Term Budget Outlook (p. 34, p. 65, fn. 5). CBO has provided us with unpublished forecasts of median real wages, which we believe are more relevant to estimating the VSL of the average person affected by transportation-related safety risks. We use these projected median real wage forecasts in our guidance for adjustments of future VSLs.

 $[\]frac{http://www.cbo.gov/sites/default/files/cbofiles/attachments/06-05-Long-Term_Budget_Outlook.pdf}{http://www.cbo.gov/sites/default/files/cbofiles/attachments/43288-LTBOSuppTables.xls}$

²⁰ 1.0107^1.0 = 1.0107 (annual income growth factor of 1.0107, raised to the power of the income elasticity, 1.0, yields annual real VSL growth of 1.0107).

²¹ Rebecca S. Spicer and Ted R. Miller. "Final Report to the National Highway Traffic Safety Administration: Uncertainty Analysis of Quality Adjusted Life Years Lost." Pacific Institute for Research and Evaluation. February 5, 2010. http://ostpxweb.dot.gov/policy/reports/QALY Injury Revision PDF Final Report 02-05-10.pdf

utility weights, based on QALY research considered "best," as presented in Table 9 of the cited study. The rate at which disability is discounted over a victim's lifespan causes these percentages to vary slightly, and the study shows estimates for 0, 3, 4, 7, and 10 percent discount rates. These differences are minor in comparison with other sources of variation and uncertainty, which we recognize by sensitivity analysis. Since OMB recommends the use of alternative discount rates of 3 and 7 percent, we present the scale corresponding to an intermediate rate of 4 percent for use in all analyses. The fractions shown should be multiplied by the current VSL to obtain the values of preventing injuries of the types affected by the government action being analyzed.

Table 2: Relative Disutility Factors by Injury Severity Level (AIS)
For Use with 3% or 7% Discount Rate

AIS Level	Severity	Fraction of VSL
AIS 1	Minor	0.003
AIS 2	Moderate	0.047
AIS 3	Serious	0.105
AIS 4	Severe	0.266
AIS 5	Critical	0.593
AIS 6	Unsurvivable	1.000

For example, if the analyst were seeking to estimate the value of a "serious" injury (AIS 3), he or she would multiply the Fraction of VSL for a serious injury (0.105) by the VSL (\$9.1 million) to calculate the value of the serious injury (\$955,000). Values for injuries in the future would be calculated by multiplying these Fractions of VSL by the future values of VSL (calculated using the formula on page 8).

These factors have two direct applications in analyses. The first application is as a basis for establishing the value of preventing nonfatal injuries in benefit-cost analysis. The total value of preventing injuries and fatalities can be combined with the value of other economic benefits not measured by VSLs, and then compared to costs to determine either a benefit/cost ratio or an estimate of net benefits.

The second application stems from the requirement in OMB Circular A-4 that evaluations of major regulations for which safety is the primary outcome include cost-effectiveness analysis, in which the cost of a government action is compared with a non-monetary measure of benefit. The values in the above table may be used to translate nonfatal injuries into fatality equivalents which, when added to fatalities, can be divided into costs to determine the cost per equivalent fatality. This ratio may also be seen as a "break-even" VSL, the value that would have to be assumed if benefits of a proposed action were to equal its costs. It would illustrate whether the costs of the action can be justified by a VSL that is well within the accepted range or, instead, would require a VSL approaching the upper limit of plausibility. Because the values assigned to prevention of injuries and fatalities are derived in part by using different methodologies, it is useful to understand their relative importance in drawing conclusions. Consequently, in analyses where benefits from reducing both injuries and fatalities are present, the estimated values of injuries and fatalities prevented should be stated separately, as well as in the aggregate.

While these injury disutility factors have not been revised in this update of our VSL guidance, the peer review process for this guidance raised the question as to whether their accuracy could be further improved. We therefore believe that a more thorough review of the value of preventing injuries is warranted. While the results of that review are not incorporated in this guidance, we plan to incorporate the results of that review in future guidance as soon as it is completed.

Recognizing Uncertainty

Regulatory and investment decisions must be made by officials informed of the limitations of their information. The values we adopt here do not establish a threshold dividing justifiable from unjustifiable actions; they only suggest a region where officials making these decisions can have relatively greater or lesser confidence that their decisions will generate positive net benefits. To convey the sensitivity of this confidence to changes in assumptions, OMB Circular A-4 and Departmental policy require analysts to prepare estimates using alternative values. We have previously encouraged the use of probabilistic methods such as Monte Carlo analysis to synthesize the many uncertain quantities determining net benefits.

While the individual estimates of VSL reported in the studies cited above are often accompanied by estimates of confidence intervals, we do not, at this time, have any reliable method for estimating the overall probability distribution of the average VSL that we have calculated from these various studies. Consequently, alternative VSL values can only illustrate the conclusions that would result if the true VSL actually equaled the higher or lower alternative values. Analysts should not imply a known probability that the true VSL would exceed or fall short of either the primary VSL figure or the alternative values used for sensitivity analysis. Kniesner et al. (2012) suggest that a reasonable range of values for VSL is between \$4 million and \$10 million (in 2001 dollars), or \$5.2 million to \$12.9 million in 2012 dollars. This range of values includes all the estimates from the eight other studies on which this guidance is based. For illustrative purposes, analysts should calculate high and low alternative estimates of the values of fatalities and injuries by using alternative VSLs of \$5.2 million and \$12.9 million, with appropriate adjustments for future VSL values and for values of injuries calculated using the VSL.

Because the relative costs and benefits of different provisions of a rule can vary greatly, it is important to disaggregate the provisions of a rule, displaying the expected costs and benefits of each provision, together with estimates of costs and benefits of reasonable alternatives to each provision.

This guidance and other relevant documents will be posted on the Reports page of the Office of Transportation Policy website, http://www.dot.gov/policy. Questions should be addressed to Jack Wells, (202) 366-9224, or jack.wells@dot.gov.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

July 29, 2011

EPA-SAB-11-011

Honorable Lisa P. Jackson Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Subject: Review of Valuing Mortality Risk Reductions for Environmental Policy: A White Paper (December 10, 2010)

Dear Administrator Jackson:

The EPA's National Center for Environmental Economics (NCEE) requested the Science Advisory Board's (SAB) advice on how the Agency should value mortality risk reductions in its benefit-cost analyses of environmental policy. The NCEE asked the SAB to review its White Paper entitled "Valuing Mortality Risk Reductions for Environmental Policy" (December 2010). To respond to this advisory request, the SAB's Environmental Economics Advisory Committee (EEAC) was augmented with additional experts with expertise in valuing mortality risk reductions.

The White Paper recognizes a longstanding problem with the term "value of statistical life" (VSL). A "statistical life" has traditionally referred to the aggregation of small risk reductions across many individuals until that aggregate reflects a total of one statistical life. For example, a one year decrease in average risk of mortality in the U.S. of 1 in a million would result in 310 "statistical lives" saved (given a population of 310 million). The VSL has been a shorthand way of referring to the monetary value or tradeoff between income and mortality risk reduction, i.e. the willingness to pay for small risk reductions across large numbers of people, but it has led to confusion because many have interpreted it as referring to the loss of identified lives. In recognition of the confusion and controversy caused by the VSL term, the White Paper proposed replacing the VSL term with "value of mortality risk." The SAB enthusiastically endorses a terminology change, but in our view, a term like "value of risk reduction" (VRR) would better communicate the notion that value is derived from reducing risks rather than the risks themselves. While the SAB recommends this terminology, we recognize that we are not experts in risk communication and suggest that EPA consider focus groups or some other mechanism to explore the language that best communicates this concept to the public. Public engagement is needed to dispel common misconceptions around this issue.

When valuing risk reduction, it is important to communicate exactly what kind of risk is being reduced since the public may value reducing risk of one kind of mortality (e.g., cancer mortality) differently from reducing risk of another kind (e.g., traumatic injury). The White Paper notes that research suggests that people are willing to pay more for mortality risk reductions that involve cancer than for risk reductions from accidental injury, and proposes a placeholder value that could be used for this cancer differential while the Agency pursues long-term research to differentially value other types of risks. The SAB agrees that values for risk reductions are not "one size fits all" and endorses the Agency's proposal to apply different values to different type of risk contexts. The SAB encourages the Agency to explore alternative methods identified in this report for estimating these context-specific values from the available research base.

The White Paper correctly notes that the amount of money people would be willing to pay for "public" risk reductions (that affect everyone) can differ from willingness to pay for "private" risk reductions (that affect only the individual or household). While this is conceptually true, the empirical literature is not yet sufficiently developed to be able to adapt values for altruistic concerns in benefit-cost analysis. Thus, at present, the SAB recommends that EPA include estimates of willingness to pay for both public and private risk reductions without distinguishing between the two.

The SAB was asked a number of technical questions about EPA's database of mortality risk reduction values and the most appropriate statistical approach for deriving a value for mortality risk reduction from existing studies. In this report, the SAB offers specific recommendations on criteria that should be used to select studies for inclusion in the database. The report also discusses how these studies could be used in meta-analysis or other approaches to estimate appropriate values of risk reduction. The SAB supports the Agency's plan to update its estimates for valuing risk reduction on a regular basis. The estimates that the Agency currently uses are based on studies that are at least 20 years old and do not take into consideration the wealth of newer studies that make use of better techniques, better data, and that better reflect current conditions. To avoid using estimates based on outdated research in the future, the Agency should establish a protocol for updating regularly the estimates of the value of risk reduction that it uses in its work.

Lastly, this SAB report does not address the complex social and political context for benefit-cost analysis in environmental policy. The White Paper described the valuation challenge facing the Agency and the different contexts underlying existing mortality risk reduction values. Thus, the SAB EEAC applied its expertise toward the analytic and empirical challenges described in EPA's eight charge questions and thus limited its scope to these topics. It should be noted that the Agency's White Paper only addressed valuing mortality risk reductions for adults. Accordingly, the SAB did not address the challenges associated with valuing children's risk reductions except to encourage the Agency to devote resources to research on this deserving topic.

Thank you for the opportunity to provide advice on this White Paper. The SAB looks forward to receiving the Agency's response.

Sincerely,

/signed/

Dr. Deborah L. Swackhamer Chair Science Advisory Board /signed/

Dr. Catherine L. Kling Chair Environmental Economics Advisory Committee

Enclosures

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory committee providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. Reports of the EPA Science Advisory Board are posted on the EPA Web site at: http://www.epa.gov/sab.

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Dr. Angela Nugent, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board Staff Office, Washington, DC

Dr. Holly Stallworth, Designated Federal officer, U.S. Environmental Protection Agency, Science Advisory Board Staff Office, Washington, DC

Table of Contents

1.	EXECUTIVE SUMMARY	
2.	BACKGROUND	4
3.	GENERAL COMMENTS	5
4.	RESPONSES TO CHARGE QUESTIONS	9
	4.1. Question 1 - Terminology	9
	4.2. QUESTION 2 – CANCER DIFFERENTIAL	
	4.3. QUESTION 3 – PUBLIC AND PRIVATE RISK REDUCTION	
	4.4. QUESTION 4 – STATED PREFERENCE AND HEDONIC WAGE STUD	
	4.5. QUESTION 5 – INCOME ELASTICITIES	
	4.6. QUESTION 6 STATISTICAL APPROACH	
	4.8. QUESTION 8 – BENEFIT FUNCTION TRANSFER APPROACH	
5.	REFERENCES	28
AP	PPENDIX A: EPA'S CHARGE TO THE SAB	A-1

1. EXECUTIVE SUMMARY

This report was prepared by the Science Advisory Board (SAB) Environmental Economics Advisory Committee Augmented for Valuing Mortality Risk Reduction (the "Committee") in response to a request by EPA's National Center for Environmental Economics (NCEE) to review its draft White Paper "Valuing Mortality Risk Reductions for Environmental Policy" (December 10, 2010). The Committee, augmented with additional experts, deliberated on the charge questions during a January 20 – 21, 2011 a face-to-face public meeting and a subsequent public conference call on March 14, 2011 was approved by the Chartered SAB at a public teleconference call on June 7, 2011. Three topics were highlighted in the charge questions: EPA's proposed terminology change, willingness to pay for cancer risk reductions, and the treatment of altruism. Other charge questions covered the selection criteria for inclusion in EPA's database of studies, the income elasticity of mortality risk reduction values, EPA's statistical approach for deriving an estimate, more timely updates to the Agency's guidance, and other methods for valuing health risk reduction. This Executive Summary highlights the SAB's major findings and recommendations.

EPA's Proposed Terminology Change (Charge Question 1). The White Paper discusses problems associated with the popular misunderstanding of the "value of statistical life" (VSL) metric that has traditionally been used in benefit-cost analysis. The VSL concept arose in benefit-cost analysis to express society's willingness to pay (WTP) for health risk reductions. Since environmental policies that reduce mortality risks also impose costs, information about the resulting benefits is necessary to determine whether the benefits of the improvements outweigh the costs. One category of benefits is captured by society's willingness to pay for health risk reductions. Much indignation has been expressed in public and political settings over the VSL term because it is often perceived as the value of life itself or the value of an individual's life when, in fact, the term is meant to refer to society's willingness to pay for small changes in risk. In the jargon of economics, VSL describes individuals' marginal rate of substitution between health risks and income or wealth. To better communicate this concept, SAB agrees with EPA that the Agency should move away from the traditional VSL term in favor of a new term that conveys the tradeoff between income and small reductions in health risk. While the SAB favors (and use in our advisory) a term like "value of risk reduction" (VRR) or "value of mortality risk reduction", we encourage the Agency to undertake some research, possibly including focus groups, on how best to communicate this tradeoff to the public. EPA needs a term that captures the value of small risk reductions that can be aggregated over large numbers of people, not a term that is easily confused with the value of life itself. In addition to finding ways to communicate the tradeoff between income and health risk reductions, the SAB encourages the Agency to explain the type of risk to be reduced while seeking ways to differentiate willingness to pay for one kind of health risk reduction versus another. Since these values express demands for different goods by different groups of people, a single "one size fits all" metric used to express the marginal rate of substitution between health risks and income oversimplifies the many complex policy contexts in which EPA operates.

Willingness to Pay for Cancer Risk Reductions (Charge Question 2). Reducing environmental cancer risk is an important part of EPA's mission to protect human health. Thus a key question is how to account for individuals' preferences for reducing cancer risks relative to other types of health risks. In addition to cancer, many other health threats addressed by environmental policies also consist of illness profiles with long latencies and substantial periods of morbidity prior to death. EPA has correctly noted that some research finds a "cancer premium," i.e. a higher willingness to pay for cancer risk reductions than for other kinds of mortality risk reductions, though other good studies find no evidence of a differential. EPA asked the SAB to comment on a placeholder value that could be used for this cancer

premium while the Agency pursues long-term research to differentially value different types of risks. The SAB believes that the "first-cut" estimate of a 50 percent differential for cancer should be refined before application. This refinement should take into account the different comparators used in current studies (e.g., fatal accident, chronic disease) and recognize that several good studies find small differences between cancer and other risks while others find large differences.

Building from the recognition that WTP to reduce cancer risks may differ from WTP to reduce other fatal health risks, the SAB recommends that EPA work toward developing a set of estimates of VRR corresponding to policy-relevant contexts defined by the type or characteristics of the risk (e.g., associated morbidity, latency) and of the affected population (e.g., age, health, income). Economic theory and empirical evidence suggest that WTP can vary with these characteristics and that a single value of mortality risk reduction is not appropriate for all contexts. Developing this set of estimates will be challenging because the available empirical estimates do not cover all relevant contexts and there is substantial, poorly understood variation among estimates from different studies. The SAB describes several methods for developing this set of estimates and encourages EPA to evaluate the validity and relevance of these methods for informing policy analysis. Proposed approaches include: (1) using only primary estimates obtained for the specific context; (2) developing adjustment factors to transfer estimates from other contexts; (3) developing meta-regression equations and (4) structural benefit-transfer methods to characterize appropriate values across multiple contexts.

Altruism (Charge Question 3) EPA asked us to comment on how altruism should be treated in valuing risk reductions for environmental policy. The White Paper correctly notes that the amount of money people would be willing to pay for "public" risk reductions (that affect everyone) can differ from willingness to pay for "private" risk reductions (that affect only the individual). Differences may be a result of altruism, either paternalistic or pure (also called non-paternalistic). Pure altruism occurs when altruists respect the preferences of the beneficiary and care about the net welfare effect on the beneficiary. Paternalistic altruism occurs when benefactors substitute their own preferences for that of the beneficiary, e.g., care about the risk reduction but not about any costs imposed on the beneficiary. The literature is clear that values driven by paternalistic altruism should be counted while values driven by pure altruism need not be counted as they do not affect the sign of net benefits. (Preferences concerning the distribution of benefits or costs in the population affect the evaluation and should be counted.)

Although the theory is clear, economic analysis has not evolved to the point of being able to separately measure portions of total value attributable to paternalistic and non-paternalistic altruism. In addition, there is little empirical evidence that altruistic concerns are significant drivers of values for risk reduction. Thus, at present, the SAB recommends that EPA include estimates of willingness to pay for both public and private risk reductions without distinguishing between the two.

Database Development (Charge Question 4). EPA asked the SAB about inclusion criteria for its database of stated preference and hedonic wage studies. Specific recommendations are offered in response to EPA's questions about selection criteria and weaknesses in data sets in the attached report. With regard to concerns about whether and how to combine results from stated preference and revealed preference studies, the SAB judges that the distinction between study type is less important than accounting for differences in risk and individual characteristics.

Income Elasticities (Charge Question 5). The Agency asks for advice concerning procedures for updating its values to account for income growth. The SAB notes that the decision on how to adjust values of risk reduction (VRR) for income growth over time is related to the approach used to estimate

the VRR (or range of VRRs) for a particular application. The SAB recommends developing estimates of income-elasticity as part of the process used to estimate appropriate VRRs for different contexts described above.

Updating Values of Risk Reduction (Charge Questions 6 and 7). The Agency requested guidance on whether it was sensible to use a simplified approach for updating the values of risk reduction using a set of available studies to fit a parametric distribution. The SAB strongly endorses EPA's proposal to update VRR estimates routinely as improved information becomes available and urges the Agency to establish a protocol for regular updates. The current estimates depend upon studies that are 20-35 years old and it is time to take advantage of a wealth of new studies and better data. In principle, any of the methods described above for estimating VRRs in different contexts could be updated to include new literature.

Long-Term Research (Charge Question 8). To support improved value estimates in the longer term, the SAB encourages EPA to work toward using structural preference functions, although the SAB believes that it will be some time before such an approach will be ready for implementation. The Agency also should encourage research to obtain revealed and stated preference estimates for the types of risk and types of affected populations that are most relevant to environmental policy contexts.

2. BACKGROUND

Reductions in mortality risk constitute the largest quantifiable benefits category of many of EPA's rules and regulations. As such, mortality risk valuation estimates are an important input to EPA's benefit cost analyses. EPA has historically used a value of statistical life (VSL) to express the benefits of mortality risk reductions in monetary terms for use in benefit cost analyses of its rules and regulations. EPA has used the same central default value (adjusted for inflation) in its primary analyses since 1999 when the Agency updated its *Guidelines for Preparing Economic Analyses* (2000). EPA's *Guidelines* advise analysts to use a central VSL estimate of \$4.8 million in 1990 dollars which converts to \$6.2 million in 2002 dollars.

Prior to the release of the *Guidelines*, EPA sought advice from the Science Advisory Board (SAB) on the appropriateness of this estimate and its derivation. In 2000, EPA also consulted with SAB on the appropriateness of making adjustments to VSL estimates to capture risk and population characteristics associated with fatal cancer risks (USEPA 2000). The SAB responded with the report, "An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Cancer Risk Reduction" (EPA-SAB-EEAC-00-010). In 2004, EPA consulted with the SAB on questions related to appropriate methodologies for valuing life extensions of different lengths and the use of meta-analysis to combine estimates from the literature. In 2006, the SAB reviewed an EPA paper on the application of meta-analysis techniques to deriving estimates for the value of mortality risk reduction as well as a paper on appropriate and available methods for valuing mortality risk reductions when affected populations have relatively short remaining life expectancy. In 2007, the SAB responded with "SAB Advisory on EPA's Issues in Valuing Mortality Risk Reduction" (EPA-SAB-08-001).

In 2010, EPA's National Center for Environmental Economics issued its draft White Paper "Valuing Mortality Risk Reductions for Environmental Policy: A White Paper (December 2010) and requested an SAB review. Augmented with additional experts, the SAB's Environmental Economics Advisory Committee met on January 20 – 21, 2011 to deliberate on NCEE's questions (found in Appendix A) and teleconferenced on March 14, 2011 to finalize its draft report. This report was approved by the chartered SAB on June 7, 2011.

3. GENERAL COMMENTS

To frame the responses to the charge questions, this report provides some perspective on the concept of valuing mortality risk reduction and its use in estimating the benefits of environmental policies. This perspective is followed by responses to the specific charge questions.

The economic theory concerning valuation of reductions in mortality risk is well developed but application to evaluation of environmental policies is challenging. First, there is a limited set of empirical studies available for reliably determining values of mortality-risk reduction and how these values depend on characteristics of the risk and affected population. Second, the conventional term used to describe the value of risk reduction (the "value of a statistical life," or VSL) is easily misinterpreted, leading to confusion about key concepts. As discussed below, the SAB applauds EPA's proposal to adopt an alternative to the conventional term and use the term "value of risk reduction" (VRR) in our discussion.

From an economic perspective, VRR is an individual- and risk-specific value defined as the individual's marginal rate of substitution between money and mortality risk. It has units of dollars per change in probability of death in a specified time period (e.g., the current year). This marginal rate of substitution can be used to estimate the money value of a small change in risk (by multiplying the change in probability by the rate); analogously, the rate is often estimated from information about the monetary value that an individual judges to be equivalent to a small change in risk.

VRR is often characterized using the maximum amount an individual could pay for a risk reduction without making himself worse off. In other words, an individual's willingness to pay (WTP) for a risk reduction Δp is defined as the amount of money such that the individual is indifferent between his initial position (with initial risk and wealth) and a position in which his mortality risk (in the specified period) is reduced by Δp and his wealth is reduced by WTP. Alternatively, one can define VRR using the amount of money the individual would require as compensation to forgo a risk reduction; i.e., he is indifferent between having his initial wealth with the risk reduction Δp , and forgoing the risk reduction but having his wealth increased by his willingness to accept compensation (WTA). For the small risk changes that are usually relevant to environmental policy, these two estimates of VRR (WTP/ Δp and WTA/ Δp) should be nearly equal.¹

Economic theory implies that VRR is likely to depend on characteristics of the individual and the risk. Five key implications of standard theory for valuing mortality risk are highlighted below.

First, the amount of money an individual judges as equivalent to a change in risk (both WTP and WTA) should be larger for a larger risk change. Moreover, for small changes in risk (for which WTP or WTA is a small share of wealth or income), the money value should be nearly proportional to the risk change, which is equivalent to saying the rate of substitution between money and the change in risk is nearly

¹ In this example, WTP is the compensating variation and WTA is the equivalent variation for the risk reduction. One can also define VRR using WTA compensation for a risk increase (i.e., compensating variation for a risk increase) and WTP to prevent a risk increase (i.e., equivalent variation for a risk increase). Under conventional economic theory, these two values of VRR should be identical to the two defined in the text for infinitesimally small risk changes. Empirically, estimates of WTA are often much larger than estimates of WTP, as discussed in response to charge question 4.a.i (Stated Preferences Studies).

constant (e.g., if a risk reduction of one in one million is worth \$10, then an otherwise similar risk reduction of two in one million is worth \$20).²

Second, VRR depends on the individual's wealth or income, i.e., on his ability to pay. It seems intuitive and is consistent with economic theory and empirical evidence that a richer person will generally be willing to pay more for (and demand greater compensation to forgo) a risk reduction.

Third, VRR is likely to depend on other individual characteristics, such as age, life expectancy, future health prospects, responsibility to care for dependents, and other factors. Intuitively, the benefit of surviving the current period depends on the future conditions one is likely to face, and the opportunity cost of spending money to improve survival (or of accepting compensation to forgo an improvement) depends on other demands on an individual's wealth. For these factors, however, economic theory does not provide clear implications and empirical estimates are limited in coverage and quality.

Fourth, VRR is likely to depend on other characteristics of the risk, including both objective and subjective characteristics. Objective characteristics include latency (time between exposure and subsequent illness or death) and the duration and severity of associated morbidity (these attributes can be described as an "illness profile"). Subjective characteristics include the extent to which the hazard which presents the risk is perceived as under the individual's control, voluntarily accepted, familiar, well-understood, and dreaded. Again, theory and empirical evidence provide only limited information on how these factors affect VRR.

Fifth, the monetary value to an individual of any given program to reduce mortality risk may also depend on program characteristics in addition to the individual's personal risk reduction. For example, individuals may have different values for risk reductions provided through public goods that affect other people (such as cleaner ambient air) and risk reductions provided through private goods that affect only themselves or their households (cleaner indoor air at their residence). Their values may also depend on the distribution of risk reductions within the population (e.g., whether disadvantaged populations are disproportionately affected) and the mechanism through which costs are paid (e.g., income taxes, electricity prices).

Recognizing that VRR is a metric that can vary with both individual and risk characteristics, the conceptually appropriate method to estimate the benefits to the U.S. population of a change in mortality risk that results from environmental policy is to estimate the risk changes faced by each individual over time, value these changes using the appropriate individual VRRs, and sum the results over the population. In contrast, an alternative "short-cut" approach is conventionally applied. The short-cut approach is to multiply the number of people in the population by the population-mean risk reduction (yielding the number of "lives saved") and multiply that by the population-mean VRR. The short-cut

² Many stated-preference studies estimate that the rate of substitution between money and risk change varies substantially with the magnitude of otherwise similar small risk changes. If this finding accurately represents individuals' preferences, it implies that individuals' indifference curves between wealth and the probability of surviving the specified time period are sharply curved or kinked within the range of survival probabilities in question. It seems implausible that different individuals, facing different initial mortality risks, will have sharp curves or kinks in their indifference curves in precisely the small regions needed to account for this empirical finding and more plausible that the finding reflects a limitation of stated-preference methods. Sharply diminishing marginal WTP with the size of the risk reduction implies that an individual would value a second risk reduction of Δp much less than an initial risk reduction of Δp . This seems unreasonable, from the perspectives of economic theory and common sense, except when payment for the initial risk reduction substantially reduces ability to pay for the second increment. If it were accepted as a valid description of individual preferences, then valuation of environmental policies would need to account for it by using sharply different VRRs for individuals obtaining larger and smaller risk reductions (Hammitt and Treich 2007).

approach yields an approximation to the conceptually appropriate method. It requires information on only the average VRR and risk reduction, not on how VRR and risk reduction vary across individuals. The approximation is exact when any of three conditions hold: (a) all individuals face the same risk reduction; (b) all individuals have the same VRR; or (c) individual risk reductions and VRRs are uncorrelated in the population. If none of these conditions holds, the short-cut approach introduces bias as a result of "premature aggregation" (Cameron 2010, Hammitt and Treich 2007).

Because appropriate valuation of reductions in mortality risk generally requires information on how VRR varies among individuals and with risk characteristics, the SAB recommends that EPA orient its approach toward (a) recognizing the conceptually appropriate method to estimate population benefits and (b) developing a set of estimates of VRR for policy-relevant cases characterized by risk and individual characteristics (or a function relating VRR to risk and individual characteristics). This orientation would be a departure from the older notion of identifying "the value of a statistical life" that is appropriate for policy evaluation. (EPA has already moved away from this older notion, e.g., by recognizing that cancer risks may be valued differently than fatal injury risks.) The SAB recognizes that developing a set of context-specific VRRs will be challenging, due to limitations of the empirical literature. This implies that, for the near term, place-holder values will be needed for many contexts, perhaps obtained using VRRs estimated for other contexts with or without adjustment. Nevertheless, the SAB recommends that economic evaluation of environmental policies specify the conceptually appropriate approach and explicitly acknowledge the necessity to apply pragmatic proxies for that ideal given data limitations.

Conceptually appropriate, context-specific estimates of VRR should account for uncertainty about the VRR for each case, ideally as a probability distribution. Developing this set of estimates is challenging because of limited theoretical guidance and empirical evidence concerning how VRR varies with risk and individual characteristics. Moreover, estimates of VRR are highly variable, both within and between studies. This variability makes it difficult to distinguish differences in VRR associated with risk and individual characteristics from random variation and from differences in study design. Many effects of study characteristics on VRR estimates are not well understood. In estimating the VRR for each case, one confronts a tradeoff between using only studies that are specifically relevant to that case and using estimates for other cases, whether neighboring or more distant, perhaps by estimating a functional relationship of values to risk and individual characteristics. The former choice will tend to minimize bias at the cost of higher variance, especially variance of the difference in valuation between cases. It may even lead to illogical differences in VRR between cases. The latter choice will tend to increase bias but reduce variance and provide a smoother relationship between values and characteristics.

While it is clear from economic theory that individual WTP may vary with individual and risk characteristics, the SAB acknowledges that the objectives, methods, and principles underlying benefit-cost analysis and particularly the values of mortality risk reductions and other non-market goods are often misunderstood or rejected as inappropriate by many participants and commentators on the policy-making process. In the past, for example, the Agency was criticized for considering VRRs that differ by individuals' age. However, as acknowledged in the White Paper, values for health risk reductions are not "one size fits all." Applying a willingness to pay value to a targeted population (such as low income or elderly) that exceeds that group's willingness to pay for reduced risk could result in decisions that ultimately reduce the well-being of the targeted group. The proposed change of terminology and application of VRRs that differ with individual and risk characteristics provide an opportunity for constructive engagement with the public and other interested parties concerning these topics.

Finally, the SAB notes that the White Paper and most of the charge questions concern technical issues concerning methods for valuing reductions in mortality risk to adults for use in benefit-cost analysis. The SAB did not engage in a broader evaluation of the appropriateness of benefit-cost analysis for evaluating environmental regulations, methods for valuing mortality risk reductions to children, or other topics that were outside the scope of the White Paper and charge questions. While the White Paper focuses on values for risk reductions for adults, values of reducing children's risk are not as well understood, thus this is a topic deserving of EPA's attention and resources for research.

4. RESPONSES TO CHARGE QUESTIONS

4.1. Question 1 - Terminology

Current EPA guidelines and standard practice use "Value of Statistical Life" (VSL) as the metric for valuing mortality risks. Section 3.1 of the White Paper discusses the VSL terminology commonly used in mortality risk valuation exercises in greater detail. The White Paper suggests that the Agency move away from using the traditional VSL terminology in favor of a new term for estimates of the marginal rate of substitution between health risks and income (see section 3.1). Specifically, the White Paper suggests that the Agency refer to these estimates as the "value of mortality risk," and report the associated units using standard metric prefixes to indicate the size of the risk change, e.g., \$/mr/person/yr (dollars per milli[10-3]-risk per person per year), or \$/µr/person/yr (dollars per micro[10-6]-risk per person per year), etc. Does the Committee agree that the Agency should pursue such a change? Does the Committee believe that making these changes would ease or exacerbate the misunderstandings documented by Cameron (2010)? Would some other terminology or approach be preferable? Please explain.

The SAB strongly supports replacing the "value of statistical life" (VSL) with a term that more accurately reflects what is being measured. The SAB encourages EPA to consider replacing VSL with "value of risk reduction" (VRR) and using VRR to delineate different types of risk. For example, there might be a VRR for sudden workplace death, a VRR for cancer death, a VRR for heart disease, and so forth. VRRs might also vary demographically (e.g., a VRR for cancer death for men 40 to 50 years old). The SAB chose not to recommend standard units but did discuss micro-risk, milli-risk and nano-risk as obvious possibilities. The best units to use will depend on the policy context, the level of aggregation, and the way in which VRR will be used.

The EPA's White Paper proposed the terminology "value of mortality risk" (VMR) to replace VSL. The SAB believes that the new term should include "reduction" since the value is typically derived from a reduction in risks rather than from the risks themselves and used to value risk reductions. Also, VMR gives the impression that people have a positive value for risk. Using risk reduction avoids this confusion. The SAB also believes that using "mortality" does not always provide a complete description of the risks involved. Different types of risks are often intertwined in valuation studies and policies often lead to changes in mortality as well as morbidity risks. For example, the morbidity (and other factors such as dread) associated with cancer is difficult to separate from the mortality risk of cancer. Excluding "mortality" allows for VRRs that encompass a broader array of health risks. As noted above, the SAB suggests that VRRs for morbidity or mortality risks be accompanied by a policy-specific classification of the type of probabilistic outcome, the target population, etc.

While the SAB recommends the terminology VRR, we recognize that we are not experts in communication. For this reason, the SAB suggest that EPA consider testing the VRR terminology and explore alternative terminologies in focus groups, discussions, and presentations with relevant user groups. Along these lines and in response to the public misconceptions of VSL documented in Cameron (2010), the SAB recommends EPA consider conducting or sponsoring research into effective communication of VRR and its role in benefit-cost analysis to the general public. Numerous public comments in response to an article about the VSL in the popular press suggest that many people also

have difficulty with the use of the word "value." Many non-economists seem to believe that the word value means "intrinsic worth," rather than the economists' notion of willingness to pay, and they bridle at the idea that their government would presume to put a dollar value on their lives. In any event, the change from VSL to something like VRR as well as the other suggested changes (e.g., from a single value of VRR to values for specific policy-related risk changes) provide a prime opportunity to engage in effective public communication. There have been calls in the past for EPA to start research programs on public communication and recent developments in climate change communication further highlight the importance of public communication in the effectiveness of policy making and implementation.

Regardless of the exact language chosen, the SAB believes that making such a change will contribute to easing the public misunderstanding of VSL. The SAB applauds EPA's leadership in this suggestion.

4.2. Question 2 - Cancer Differential

Experts generally agree that value function transfers can outperform point value transfers in cases where the characteristics of the risks and/or the exposed populations differ between the source studies and the policy context in measurable ways. That is, the more commodity- and individual-specific attributes that can be included in the benefit transfer exercise, the better the estimate of willingness to pay. Charge questions 2 and 3 inquire about whether applications of benefits transfer methods to value mortality risk reductions from environmental pollutants can be improved by controlling for more of the attributes that distinguish the source studies from the policy scenario.

The White Paper concludes that research since the 2000 EPA Guidelines suggests that people are willing to pay more for mortality risk reductions that involve cancer than for risk reductions from accidental injury (see section 3.3). Our preliminary review suggests that a "cancer differential" of up to 50% over immediate accidental or "generic" risk valuation estimates may be reasonable. Conceptually, would the weight of evidence (both theoretical and empirical) suggest there is a cancer differential? If so, does the Committee believe that our estimate of the differential is appropriate If not, how does the Committee recommend the Agency incorporate cancer differentials in benefits analysis involving reduced cancer risks?

The SAB commends EPA for its effort to develop appropriate values for mortality risk reductions rather than applying a "one size fits all" value to all cases. As discussed in the introductory section, theory suggests that VRR depends on characteristics of the risk and the individual.

As noted, charge questions 2 and 3 inquire about the use of benefit-transfer methods. Charge questions 4-7 are also concerned with issues of inferring the appropriate VRR for a specific application from available studies. As explained in the introductory section, SAB recommends that EPA work toward developing a set of estimates of VRR for policy-relevant cases characterized by risk and individual characteristics. There are strong precedents for applying benefit-transfer methods to analyze non-health benefits of EPA policies. In that context, as with VRR, analysts confront choices between how much to rely on estimates that are specific to the application and how much to "borrow information" or extrapolate from estimates that are less similar to the application (in the present context, how much to adjust for differences in attributes between the risk valued in source studies and the policy-relevant risk). There is no general answer to this problem. The best approach will be sensitive to the quality and number of available studies that estimate relevant values. In the case of death from traumatic injury, the

³ See Binyamin Appelbaum, "As U.S. Agencies Put More Value on a Life, Businesses Fret," New York Times, February 16, 2011 and the inventory of public comments available at http://pages.uoregon.edu/cameron/vita/Stakeholder_misconceptions.pdf.

set of empirical estimates is rich, including revealed-preference studies of wage differentials and consumer products (e.g., motor vehicles) and stated-preference studies of transportation hazards. For other applications, the empirical literature is much more limited and often includes only stated-preference studies.

Given this background, SAB recommends that EPA explore alternative methods to estimate a distribution of appropriate VRRs for relevant cases (e.g., deaths associated with exposure to airborne fine particulate matter, fatal cancers associated with exposure to environmental carcinogens). Below, the SAB suggests four possible methods. It may be appropriate to use different methods for different policy-relevant cases to reflect differences in the number and quality of relevant studies and differences in the characteristics of the risk reductions they value.

One approach would be to develop independent estimates for relevant cases, using only studies that are closely matched on risk and individual characteristics. This approach may be useful for some cases but not others, due to the limited coverage of the empirical literature.

A second approach would be to develop a baseline distribution of estimates (perhaps for fatal injury) and a set of adjustment factors for risk and individual characteristics as warranted. Such adjustment factors might be developed for hazard characteristics (e.g., one or more cancer differentials appropriate for different types of cancer), individual characteristics (e.g., adjustment factors for age and income), and program characteristics (e.g., public programs versus private risk reductions). This approach could incorporate both direct estimates of VRR for different risks and risk-tradeoff studies that estimate only differentials in VRR between risks. This approach and the first approach could be informed using formal expert elicitation to identify the studies that are sufficiently closely matched to the policy context of interest and/or to estimate distributions of baseline estimates and adjustment factors.

A third approach would be to develop a meta-regression model to estimate VRR as a function of risk and individual characteristics. The historical EPA approach, using the mean of 26 studies, is an example of a meta-regression including only one term (an intercept). This approach could be extended to include a small number of categorical or indicator variables (e.g., for cancer type, age or income categories) and/or a small number of continuous variables (e.g., income or its logarithm). It may be appropriate to include variables describing study type (notably stated or revealed preference) to avoid confounding estimates of risk and individual characteristics with (poorly understood) effects of study type (at minimum, one should test for sensitivity to study type). Such a meta-regression can be viewed as a reduced-form or first-order approximation of a more complicated function relating VRR to risk and individual characteristics.

A fourth approach would be to develop and estimate a structural preference function. An advantage of this approach is that its structure is consistent with economic theory, and so extrapolation from existing estimates can be performed with greater confidence (e.g., it may be possible to develop improved estimates of how VRR depends on the magnitude of the risk reduction). Moreover, it provides a method for incorporating other types of information, in addition to estimates of VRR, that are informative about individual preferences regarding mortality risk reduction. (As described in response to charge question 8, SAB judges that the structural-preference-function approach requires further development and testing before it should be relied on as a primary source of VRR estimates.)

In evaluating the different approaches, one criterion is the degree of fit between the resulting estimated distribution for VRR in each specific context and the results from high-quality studies that estimate

VRR for that context directly. A second criterion is the intuitive plausibility of the pattern of VRR distributions across contexts.

In estimating VRRs and how they vary with risk and individual characteristics, the SAB suggests caution in using results from non-US populations. The effects of individual and population characteristics on VRRs may be sensitive to health-care and social-welfare programs and other factors that differ significantly between countries.

In response to charge question 2, SAB recognizes that cancer is (after fatal injury) the risk for which the empirical literature provides the most information. In addition, there are some estimates of VRR for respiratory and other chronic disease. The SAB concurs with EPA's judgment that only the studies that compare values for cancer and other risk reductions are useful for evaluating possible differentials. These include valuation studies of two or more types of fatal risk and risk-tradeoff studies. Stated- and revealed-preference studies of only one type of risk, without internal comparison, are not useful because there is too much unexplained variation between studies to determine how much of the differential is associated solely with risk characteristics.

The SAB believes that the "first-cut" estimate of a 50 percent differential for cancer should be refined before application. This estimate is justified in the White Paper as approximating the average differential found in nine studies (reported in footnote 14, page 25). However, no control is made for the fact that different studies evaluate different types of cancer and compare it against different risks (e.g., injury, other disease) and the differential associated with the Van Houtven et al. (2008) study is misreported (the proportional WTP is 3 times higher but the differential is 2). Any quantitative estimate of a cancer differential will be sensitive to the weight given to the Van Houtven et al. study, which estimates a much larger effect than any of the other studies. (Note that six of the nine reported studies yield estimates between -0.15 and +0.30).

Finally, in evaluating hazard-specific differentials it is important to distinguish between differentials that are conditional on characteristics of the illness profile (e.g., duration and severity of morbidity, latency) and differentials that do not control for these characteristics. In evaluating values of faster vs. slower deaths (e.g., from injuries vs. cancers), it seems important to control for whether the period of morbidity extends life or shortens the period of healthy life (i.e., is the comparison between instantaneous death and manifestation of a fatal disease at the same time or between instantaneous death and death from chronic disease at the same time?). In addition, some studies provide information on valuation of different types of cancer, suggesting that there is no single differential that is appropriate for all cancers.

In sum, the SAB suggests that the magnitudes of cancer and other hazard-specific differentials should be evaluated as part of an integrated process used to estimate the value of mortality risk reduction and how it varies with risk and individual characteristics, using some of the methods described above.

4.3. Question 3 – Public and Private Risk Reduction

Environmental policies generally provide public risk reductions. However, research, particularly stated preference research, provides willingness to pay estimates for both public risk reductions as well as private risk reductions. And, some research indicates that individuals' willingness to pay for public risk reductions may be different than that for private risk reductions. One factor that may contribute to these differences is altruism, which, all else equal, should make values for public risk reductions larger than those for private risk reductions.

a. Should EPA rely on studies that estimate willingness to pay for both public and private risk reductions? If so, is it sufficient to control for this key characteristic in the modeling framework? Or, should EPA limit the analysis to studies according to the type of risk reduction in the study? If using only one type of study is recommended, should EPA use studies that estimate public or private risk reductions? If we are to limit the studies used to one type, is there a role for the excluded group?

As described above, VRR may vary with program characteristics such as public or private risk reduction. The SAB does not recommend categorically restricting inference to studies that are only private or only public but exploring the estimated magnitude of the effect. If the effect is of sufficient magnitude to warrant accounting for it in economic evaluation of a program, it can be accounted for by using only studies that are closely matched to the required application or by adjusting results from other studies.

b. Studies that estimate willingness to pay for public risk reductions may allow EPA to better capture altruistic preferences in benefit-cost analysis. Did the White Paper adequately capture the theory on how to incorporate altruism into the value of mortality risk reduction? How should altruistic preferences be treated in benefit-cost analysis? Should the Agency incorporate altruism into the value of mortality risk reductions, even if we are unable to distinguish the specific form of altruism involved (i.e., paternalistic or non-paternalistic)? More generally, what alternatives should the Agency pursue in the short-term to appropriately account for altruistic preferences when evaluating public programs, if any?

The White Paper adequately summarizes the literature on altruism in benefit-cost analysis. Values driven by paternalistic altruism are considered legitimate in benefit-cost analysis. The literature is clear that pure (non-paternalistic) altruism, in which the benefactor respects the preferences of the beneficiary, can result in over-counting benefits (e.g. Flores 2002, Bergstrom 2006). This is because welfare gains that accrue to beneficiaries, and that are valued by altruists, depend on the net value to beneficiaries. If beneficiaries were to pay exactly their value for a larger quantity of a public good, then altruists would receive no altruistic welfare gain. However if beneficiaries paid less (more) than their value, altruists would receive an altruistic welfare gain (loss). In short, pure altruists care about both the benefits received and costs paid by beneficiaries; counting only the altruistic benefits is incorrect.

While the economic literature is clear on how values driven by paternalistic and non-paternalistic concerns should be treated in economic analysis, the state of the art in economic analysis has not evolved to the point of being able to separately measure portions of total value attributable to paternalistic and non-paternalistic altruism. There is little empirical evidence that altruistic concerns are significant drivers of values for risk reduction. At present, the SAB recommends that EPA include estimates of willingness to pay for both public and private risk reductions without distinguishing between the two.

4.4. Question 4 – Stated Preference and Hedonic Wage Studies

The two primary literatures used to assess willingness to pay for mortality risk reductions are stated preference studies and hedonic wage studies. The White Paper assembles two databases summarizing studies in both literatures, capturing much of the information outlined in number 3 of

the SAB-EEAC's recommendations dated October 2007 (see section 4). ⁴ These studies, or a subset thereof, would form the basis of revised guidance in the near term as well as possible future meta-analyses.

- a. The selection criteria employed in creating the two data sets are carefully outlined in the paper (see sections 4.1.2 and 4.2.4). Please consider these criteria in answering the following questions:
 - i. Should additional criteria be added to screen studies for inclusion in the datasets? If so, please specify those criteria. Should any criteria be eliminated or modified?

The EPA assembled two databases summarizing stated preference and hedonic wage studies following the SAB-EEAC's recommendations dated October 2007 (see especially Section 4). As noted in the charge question, these criteria are intended to be used to identify appropriate studies for estimating VRR, whether as part of a meta-analysis or using some other approach, such as those identified in response to charge question 2. A set of eight criteria was used to select studies to include in each database. The objective of the selection criteria -- to exclude low-quality studies and to ensure applicability to the US -- should be stated explicitly to ensure transparency and the selection of appropriate criteria. An additional criterion that should be added is that estimates should be restricted to those obtained for appropriate risk and population characteristics when that restriction is appropriate for the approach used to estimate VRR in a particular context (see the discussion of methods described in response to charge question 2). Below are answers for each of the specific charge questions for each database separately (where appropriate). Note also that the criteria apply to studies valuing of both morbidity and mortality since both types of endpoints are relevant to measuring VRRs in different contexts.

Stated Preferences Studies

With respect to stated preference studies, the SAB provides its response to the White Paper's eight selection criteria.

(1) Minimum sample size of 100.

The SAB believes that setting a minimum acceptable sample size is not a very useful criterion. Small samples are of concern for two reasons: the precision of the estimates is likely to be low and the sample is unlikely to adequately represent a population of interest. With regard to the first point, the relationship between sample size and precision of the estimated VRR depends on the study design, e.g., for a fixed sample size, one single-bounded binary-choice valuation question provides less precision than a double-bounded binary-choice question, which provides less precision than an open-ended question. (Note that the approaches that provide more precision may induce more bias and are not necessarily better.) Similarly, choice experiments in which respondents make many choices may provide more precision than contingent-valuation studies in which respondents value only a single good. These considerations suggest that different minimum sample sizes should be developed for different types of stated preference (SP) studies, thereby compromising the simplicity of a sample-size criterion. A conceptually cleaner approach would be to develop a criterion based on precision of the estimate. The SAB understands that some SP studies do not report the precision or standard error of their estimates or information from which this can be

⁴ The recommendations included specific features of hedonic wage and stated preference studies that should be identified in the studies.

approximated. Studies that do not report quantitative information about the uncertainty in their estimates do not follow established best research practices and thus are not of adequate methodological quality for use in determining VRR. Moreover, such studies seem unlikely to meet other criteria for methodological adequacy, such as providing evidence that the results can be interpreted as valid estimates of VRR (discussed below).

With regard to the second point, studies with small samples often use convenience samples or other groups that are not representative of the general population. These studies are likely to be excluded by the second criterion, discussed below. If a study with small sample size uses a sample that is representative of the population of concern and provides adequate precision, it should be included in the analysis.

(2) Sample frame based on general population.

The SAB suggests that the sample frame be the "appropriate population" rather than the general population, to the extent practicable. The EPA should be clear in its determination of what the appropriate sample frame is and seek studies that use that sample frame or can be used to understand how to adjust results that use other sample frames. For example, if the EPA is seeking to value reductions of risks that are specific to a particular segment of the population, the study should focus on obtaining values that are relevant for members of that segment of the population. Older studies will eventually fail to adequately represent the current population so the age of the study should be evaluated to determine whether it is reasonable to consider it representative of current preferences.

(3) Conducted in a high-income country.

The SAB believes that surveys should ideally be limited to those conducted in the United States. To the extent that preferences, cultural norms, institutions, and demographic profiles can affect valuation of risk reductions, studies based on non-U.S. populations may provide biased estimates of U.S. values. Indeed, work using similar stated-preference instruments suggests there are significant differences in patterns of WTP even between countries as similar as the U.S. and Canada (Alberini et al. 2004, Cameron et al. 2010).

(4) Results based on exclusive dataset.

The SAB disagrees with this criterion. In economic research, multiple estimates for an outcome of interest (in this case, a point estimate of the VSL) are often reported which are based partially or wholly on overlapping samples. Model uncertainty, covariate-measurement uncertainty, and interest in heterogeneity of impacts across subpopulations all lead to varying outcome estimates. Rather than apply a zero weight to the information contained in all but one of the estimates arising from a single database, or from overlapping databases, the SAB recommends that the EPA include estimates based on its set of other criteria and take all estimates that meet those criteria. If possible, EPA should control statistically for within-study correlations.

- (5) Written in English.
 The SAB agrees with this criterion.
- (6) Provides enough information to calculate a WTP estimate if one is not reported in the paper. The SAB agrees with this criterion.

- (7) Provides estimates for willingness to pay (willingness to accept estimates were not included). The SAB agrees that contingent valuation studies of WTA often yield results that differ substantially from estimates of WTP (Horowitz and McConnell 2002). The presence of income effects can justify some of the difference between these value constructs, as could limited substitutability of market goods (Hanemann 1991), but the reasons for occasionally very large divergences are not clear. Thus the SAB recommends that contingent valuation estimates of WTA should not be used. A second rationale for this advice is that most environmental policies and regulations do not involve compensating individuals for environmental damages but rather individual willingness to pay the costs of policies or regulations that reduce mortality risk.
- (8) Provides estimates for willingness to pay for risk reductions to adults (estimates for risk reductions to children are not included).
 The SAB agrees that estimates of VRR for adults should be based on estimates of WTP for risk reductions to adults. Of course, the Agency also needs values for mortality-risk changes for children. VRR estimates for adults should not be automatically applied for children, so this criterion is not applicable in the case of children's risks. The SAB recognizes that there is a paucity of studies focused on estimating the value of risk reduction for children. This is clearly a research need that the Agency may wish to invest in.

The SAB recommends an additional criterion: that the stated preference study should provide evidence that it yields valid estimates of VRR. There are many factors that can influence responses to a stated-preference survey in ways that cannot be interpreted as consistent with estimating the theoretical concept of interest. For example, respondents may give answers consistent with extraordinarily high or low values (e.g., "protest zeros" in open-ended questions). One form of evidence of validity is showing that the study passes a scope test, i.e., that estimated WTP increases with the size of the risk reduction that is valued. A weak scope test demands only that WTP increase in a statistically significant way with the size of the risk reduction; a strong test demands that WTP be proportional to risk reduction (for changes in mortality risk, economic theory implies that WTP is nearly proportional to the risk change with deviations occurring primarily through the income effect (Hammitt and Graham 1999, Corso et al. 2001). External scope tests (that compare WTP between subsamples of respondents) are generally viewed as superior to internal scope tests (that compare WTP within a sample) because respondents could provide mutually consistent estimates of WTP for different risk reductions even if their response to the first valuation question is random.

Hedonic Wage Studies

With respect to hedonic-wage studies, the White Paper describes eight selection criteria, of which four are based on a recently published meta-analysis by Bellavance et al. (2009). The four based on Bellavance et al. are listed below as criteria (5) through (8). The criteria, and the SAB's recommendation regarding each criterion, are described in turn below.

(1) Use a sample size of greater than 100.

Sample size is not a significant concern for most wage-differential studies, which rely on large data sets of workers and actuarial risk estimates based on comprehensive fatality data. As noted in the discussion of stated-preference studies, sample size per se is not relevant to study quality or utility. Hedonic wage studies that are based on other sources (e.g., an original survey of workers) should be evaluated on a case-by-case basis for precision of estimates and representativeness of the sample.

(2) Limit selected studies to those conducted in high income countries as defined by the World Bank.

The SAB recommends that the EPA base its analysis only on studies conducted on U.S. populations. Because hedonic wage equations estimate an equilibrium outcome based on preferences, demographic distributions and technologies, they will be unique to each country. Even if incomes are similar across countries, similarity in other conditions that affect the revealed marginal rates of substitution between risk and wages are not assured.

- (3) Omit studies based on the Society of Actuaries risk data.

 The SAB agrees with this criterion. Charge Question 4a.ii. relates to this criterion and further comments are given in response to that charge question.
- (4) Omit studies that focused on extremely dangerous jobs (e.g., police).

 The SAB agrees this is a reasonable criterion because the population included in these studies is not representative of the population affected by EPA regulations. Should there be a case where the EPA is evaluating extreme risks to a well-defined population, research concerning the risk preferences of that population would be relevant.
- (5) Retain only studies which employ a model specification "similar to that given" $(\ln(w_i) = X_i\beta + \phi \rho_i + \mu_i)$. The SAB disagrees with this criterion if it is applied exactly as the White Paper suggests (that only cross-section OLS regressions are included in the database). For example, the criterion would imply that estimates based on panel data, instrumental variable, or quasi-experimental methods would be excluded. The SAB recommends that all estimates arising from conceptually sound methods be included.
- (6) Exclude studies based on specific cause of death.

 This criterion is appropriate when the goal is to provide an estimate of the value of reducing risks of workplace accidental deaths. The SAB notes, however, that the EPA should recognize that even within the context of accidental deaths, there is a great deal of heterogeneity (e.g., falls versus electrocution). The literature often aggregates these into a single measure of fatality risk but some new studies attempt to distinguish values by these risk characteristics (e.g., Scotton and Taylor 2011).
- (7) Exclude studies which use the same underlying sample of workers as other studies. In other words, if multiple VSL estimates are reported based on the same underlying survey sample for stated preference studies or the same worker sample for hedonic wage studies, prior recommendations suggest that only one VSL estimate from a given sample be incorporated into the meta-analysis.
 - The SAB agrees that this approach is desirable when conducting meta-analyses of clinical trials to describe efficacy of a treatment on a health endpoint, but it is not a desirable approach for meta-analyses applied to economic research. As noted above for stated preference studies, in economic research, multiple estimates for an outcome of interest (in this case, an estimate of VRR) are often reported which are based partially or wholly on overlapping samples. Model uncertainty, covariate-measurement uncertainty, and interest in heterogeneity of impacts across subpopulations all lead to varying outcome estimates. Rather than apply a zero weight to the information contained in all but one of the multiple estimates, the SAB recommends that the EPA select observations for inclusion in the metadata set or other applications based on its set of other criteria and include all estimates that

meet those criteria. Including multiple estimates from the same or overlapping data raises issues of how to account for statistical dependence among estimates and whether a study that reports more estimates should contribute more to the summary measure. There are several methods for addressing these issues described in the meta-analysis literature (e.g., Mrozek and Taylor 2002, Viscusi and Aldy 2003, Bellavance et al. 2009).

(8) Exclude studies failing to report enough information to calculate the value of mortality risk reductions and/or the average probability of death.

The SAB agrees with this criterion.

Additional comments:

The EPA should consider adding the following criteria:

- (a) Hedonic-wage regressions should include a measure for nonfatal-injury risk, or at least provide evidence concerning the sensitivity of the estimated value of mortality risk to inclusion/exclusion of nonfatal risks.
- (b) Hedonic-wage regressions should include an appropriate level of industry and occupational control variables to address the problem of unobserved job characteristics that often exists in these studies. Panel models that control for unobserved worker characteristics do little to alleviate this problem when the risk variable is constructed in such a way that it varies only by occupation and industry of the worker. Estimates from models that convincingly address unobserved job and worker characteristics using the best methods available and appropriate for the data are preferred.
- (c) Eliminate any study that relies on risk measures constructed at the industry level only (not by occupation within an industry), even if the source of the risk data is the Census of Fatal Occupational Injuries (CFOI). For example, Smith, et al. (2004) use risks that vary only by industry of the worker. While there has not been direct evidence of the degree to which this practice introduces measurement error of the type discussed by Black and Kneisner (2003) and Black, Galdo and Liu (2003), it would seem likely to introduce important measurement error.
- (d) Include only estimates that are based on an appropriate sample frame or can be used to adjust the sample frame for the policy context. This criterion follows the suggestion for criterion (2) for stated preference surveys.
 - ii. Section 4.2.2 of the White Paper discusses problems of measurement error associated with some common sources of occupational risk information among other concerns with the hedonic wage approach. Should EPA limit its selection of hedonic wage studies by the source of occupational risk information? For instance, studies relying on data from the Society of Actuaries (SOA) have been omitted from the described data set. Should the SOA studies be excluded? Should other sources be excluded as well?

EPA should exclude hedonic-wage studies that do not use adequate risk data. The quality of the risk estimates is critical to wage-differential estimates of VRR and there have been substantial improvements in risk data over time. The SOA data are not conceptually appropriate because they include deaths from non-occupational risks, for which no wage differential would be expected. Prior to 1992, Bureau of

Labor Statistics (BLS) workplace fatalities were survey estimates, which the National Academy of Sciences had questioned due to the high rate of sampling errors.⁵

Several sources provide additional details on the difficulties with past risk estimates. Drudi (1997) describes problems in constructing valid risk estimates. Black, Galdo and Liu (2003) and Black and Kneisner (2003) provide a critique of the previous risk measures and illustrate the unreliability of study estimates using these measures. Leigh (1995) highlights the issue of measurement error when using risk data that vary only by industry or by occupation of the worker. Viscusi (2004) finds that estimates of the value of mortality risk using estimates of risk by industry and occupation are roughly half as large as estimates using estimates of risk by industry.

Lastly, there has been a steady decline in overall numbers of workplace deaths since 1970. The labor force has shifted from manufacturing to service-oriented industries and exposures in the workplace have changed over time. Currently up to 15% of workplace deaths are homicides. The reliance on flawed data that are not representative of current conditions is not defensible.

In summary, all studies that rely on data of lower quality than the CFOI should be excluded.

b. Should any of the studies included in the datasets be eliminated? If so, please specify those studies and the reasons for eliminating them.

Stated Preference Studies

The SAB prefers not to endorse or exclude specific studies. The appropriate strategy will be to consider the (revised) criteria recommended above and to revisit the database of studies with these criteria in mind.

The SAB emphasizes that the studies used should adhere to best practices. The quantities being estimated should correspond to a theoretically sound microeconomic construct (i.e., based on the theory of consumer choice) that measures an appropriate concept of value. In general, these measures will involve marginal rates of substitution. Ideally, this marginal rate of substitution is between a specified risk reduction and money, which yields an estimate of willingness to pay for that risk reduction. However, risk-risk tradeoffs can also be expressed as marginal rates of substitution between risks. In combination with appropriate studies that produce marginal rates of substitution between one of the risks in such a pair and money, it may be possible to use risk-tradeoff information to calculate willingness to pay for the other risk.

Hedonic Wage Studies

All studies not based on the U.S. workforce, not based on risk data of comparable or superior quality to the CFOI data, and not adhering to the other criteria discussed above should be excluded. The first two criteria eliminate all studies prior to Viscusi (2004). Additional criteria as discussed in response to charge questions 4.a. should be developed and studies after 2003 should be evaluated on these terms.

c. Is the committee aware of relevant empirical studies in the stated preference and hedonic wage literatures that are not adequately captured in this review? If so, please provide citations.

⁵ For example, the BLS estimated there to be 2,900 workplace fatalities in 1990 while the National Safety Council estimated 10,500 and the National Institute of Occupational Safety and Health estimated 5,500 (not including Connecticut and New York and using only death certificates, which Drudi (1997) reports identify as few as 35% of workplace deaths).

There are a number of new studies that could be used to update VRR estimates using meta-analysis or other approaches. However, many of these are not published and therefore not peer reviewed. The benefits of including results from these studies are that they are likely to represent current population characteristics and preferences, use the most up-to-date methods in stated and revealed preference work, and are generally designed to elicit the values that are most policy relevant for EPA. However, these benefits must be weighed against the fact that the use of peer-reviewed literature has long been held as the gold standard of scientific credibility. Given the importance of this latter point, EPA should not rely on the "grey literature" (unpublished manuscripts, reports, dissertations, and other non-refereed materials).

The SAB wishes to emphasize that the important aspect of peer-review that needs to be adhered to is peer-review of the methods, data used to fit the models, and general approach of the study. It is not necessary that every VRR estimate or detail of a model to be transferred in a benefits-transfer context appear in the peer-reviewed publication. Thus, it would be reasonable to admit VRR estimates that are based on methods and data that have been peer-reviewed, even if those estimates are reported only in supplemental, unpublished reports (including working papers or dissertations). Similarly, if a study that estimates a WTP function has satisfied peer review, but researchers need to use parameters not reported in the peer-reviewed publication (e.g., the variance-covariance matrix for the parameters) in order to generate values for a policy-relevant context, this should also be considered to have meet the peer-review mandate.

The SAB suggests the following published studies as additional relevant empirical studies for EPA's consideration.

Other studies to consider:

Stated Preference Studies
Cameron, DeShazo, and Stiffler (2010).
Cameron, DeShazo, and Johnson (2010).

Hedonic Wage Studies
Evans and Schaur (2010).
Evans and Smith (2006).

4.5. Question 5 – Income Elasticities

Income elasticities are discussed briefly in section 5 of the White Paper. In keeping with Agency practice, we created the two databases by adjusting all estimates for income growth over time using an income elasticity value of 0.5 based on prior Agency reviews of the literature and results Viscusi and Aldy, 2003. In addition, we adjusted all estimates for inflation as well as for purchasing power parity where necessary, as recommended by the EEAC's October 2007 report. Does the Committee agree with this approach to accounting for income growth over time?

The question of how to adjust estimates of VRR before combining them in a meta-analysis is distinct from the question of how to adjust for use in policy analysis (discussed below). For meta-analysis, the SAB suggests that EPA not adjust VRR estimates for income growth but explore how VRR varies with (a) the time period to which the data pertain and (b) the average sample income as part of the meta-analysis.

Does the Committee believe the Agency should adjust its value of income elasticity for use in policy analysis in light of recent findings in the literature?

Intuition, economic theory, and empirical estimates all suggest that VRR should increase with income, and so EPA should adjust for changes in income in evaluating benefits of risk reduction. The income elasticity of VRR, like VRR itself, may vary with risk and individual characteristics.

The literature on VSL income elasticity has employed several approaches and produced a wide range of results (Hammitt and Robinson 2011), including cross-section analysis of within-sample variation in stated-preference data (e.g., Alberini et al. 2004), meta-analysis of hedonic-wage studies (e.g., Viscusi and Aldy 2003), longitudinal analysis of hedonic-wage data for a particular population (e.g., Costa and Kahn 2004), and quantile analysis of hedonic-wage data (Evans and Schaur 2010, Kniesner et al. 2010). Estimates obtained from cross-section analysis of stated-preference data range between 0.1 and 1.0 while longitudinal-study estimates range between 1.3 and 3.0. Quantile analysis yields elasticity estimates of 2.2 for the lowest decile of income and 1.2 for the highest decile of income.

Consistent with its recommendations on VRR, the SAB recommends that EPA attempt to characterize the distribution of income elasticity and how it varies with risk and individual characteristics using one or more of the approaches described for characterizing VRR.

If so, what value or range of values does the Committee believe should be used?

See previous response.

4.6. Question 6 – Statistical Approach

The White Paper describes a simplified approach for updating the Agency's recommended mortality risk value estimate(s) (see section 5.1.1). This approach involves fitting a parametric distribution to the set of estimates from selected studies. This is similar to the approach used for EPA's current default VSL estimate.

a. Should EPA pursue this approach for updating its mortality risk valuation guidance in the near term (until a more detailed analysis can be conducted)?

The SAB recommends that EPA explore some of the methods proposed above (in response to charge question 2) for estimating a distribution of VRR for relevant cases. Whichever method is used for a particular application can be updated over time. If it is not possible to develop an appropriate VRR for a particular case within the allowable time, placeholder estimates and sensitivity analysis may have to be used, but if this is done, it should be made clear how the policy context differs from the contexts within which the available WTP estimates have been measured and what assumptions are required to transfer benefit estimates to the policy context.

b. If so, should the databases on which values are based be created using only one estimate drawn from each study or multiple estimates from each study?

In general, it will be appropriate to include multiple estimates from each study (see response to charge question 4).

c. If only one estimate per study should be used, what criteria should the Agency apply in selecting the appropriate estimate? How would these criteria vary from one segment of the literature to the other? The paper describes the methods used to select independent estimates from each study. Does the Committee agree with the methods used?

Not relevant (see charge question 6b).

d. How important is it that estimates be drawn from non-overlapping subsamples? If multiple estimates per study are recommended in the construction of the meta-datasets, should the estimates be selected to avoid overlapping sub-samples?

It may be appropriate to include multiple estimates from the same subsample. As discussed in response to charge question 4, studies of VRR often explore the effects of using alternative model specifications on the estimated value. When (as is often the case) it is often not clear which specification (and resulting estimate) is most appropriate, it is preferable to include all estimates from the same (or overlapping) subsets that meet other acceptance criteria.

In other literatures, meta-analysis is sometimes used to estimate the "true" value of some physical parameter (e.g., Bell et al. 2005, Ito et al. 2005, Levy et al. 2005). Willingness to pay for a risk reduction, however, is not some fixed and immutable constant of nature; it may vary systematically with risk attributes such as the type of illness or injury, the latency of the illness, and the duration of morbidity, as well as the number of lost life-years that can be anticipated. The value of a risk reduction may also vary systematically with the characteristics of the individual, including age, gender, and income, as well as with subjective risks and other co-morbidities. Thus one sample and one model, if sufficiently general, can provide estimates of the values of different types of risk reductions to different types of people. Indeed, using one data set and a sufficiently general model to capture this heterogeneity can produce better estimates of how VRR varies with these characteristics by eliminating between-study effects.

It is also possible that the same sample can be used with different, but equally plausible, specifications to yield different estimates of the value of the same risk reduction. In cases where the best functional form is unknown and multiple alternatives yield similar measures of fit, it is appropriate to preserve information about both the variation across specifications in the different point estimates of the VRR as well as the precision (standard error) for each individual point estimate. As noted above (in response to charge question 4.a.i), when using multiple estimates from a single study or dataset, it is important to consider how to weight individual estimates and to adjust for statistical dependence among them.

e. Does the Committee still favor analyzing the stated preference and hedonic wage estimates separately? If so, how should the separate results of these analyses be used in evaluating new policies? If not, how should they be combined in a single analysis?

The effects of risk and individual characteristics on VRR may be more important than the distinction between stated preference (SP) and revealed preference (RP) studies. However, wage-differential studies and SP studies seem to yield systematically different estimates, even for reasonably similar risks (e.g., traffic fatalities). The reasons for this difference are not well understood.

In evaluating how VRR varies with context, it may be necessary to distinguish SP and hedonic wage estimates to avoid confounding effects of risk or individual characteristics with study type. This does not imply that the two literatures must be treated independently. Indeed, to the extent that each literature

provides useful information about the VRR in a particular context, or the variation of VRR between contexts, it is important to combine their results. Results from risk-tradeoff studies can also provide useful information and should be considered for inclusion. Although risk-tradeoffstudies do not provide WTP estimates, they can be used to translate estimates of WTP to reduce one type of risk into WTP to reduce other types of risks. Of course, estimation errors would have to be compounded across these two stages.

Results from hedonic-wage and SP literatures can be combined using some of the methods described in response to charge question 2. In addition, even though wage-risk studies may not address the types of illness profiles that are relevant to EPA policy contexts, these studies are vitally important for validation of SP studies. Hedonic-wage estimates can serve as a benchmark for evaluating stated-preference estimates of the value of the "sudden death in the current period" illness profile. Consistency between SP and best-practices RP studies, for comparable types of risks and populations, will remain an important criterion for cross-validation of the estimates from SP studies. (Validation is more difficult for domains of SP studies which are not overlapped by available RP studies.)

f. Would the Committee support the development and application of separate means or ranges generated from the two segments of the literature? Given separate means and/or ranges from each segment, should the results be weighted and combined to produce a single point estimate or range? If so, how? Are other presentations of the results preferable? More generally, how should uncertainty in the estimated value(s) of mortality risk reductions be handled in benefits analyses?

The use of weighted averages of individual point estimates is only appropriate if these point estimates measure the same thing. Recent research highlights heterogeneity in WTP for risk reductions as a function of both the type of risk to be reduced and the characteristics of the affected population. If multiple estimates are available for the same context, then these can be averaged, and it is appropriate to consider some sort of weighting scheme that reflects the relative precision of the different point estimates. Weights that reflect relative precision are sometimes quantified as an inverse-standard-error weighting scheme, so that more precisely estimated (i.e. more certain) values are given greater weight than less precisely estimated values. As always, it will be important to recognize the uncertainty related to the choice of a statistical model as well as the uncertainty related to the standard error of the VRR estimate from any given statistical model.

4.7. Question 7 – Standardized Protocol

We are interested in developing a standardized protocol for updating the Agency's recommended mortality risk value estimates on a regular basis—for example, every 5 years or so—to incorporate new estimates from relevant economic valuation studies as they appear in the literature. Such a protocol might be based on the approach outlined in Section 5.1.1 or something similar. This approach, combined with a set of rigorous criteria for determining which new studies and value estimates are suitable for inclusion in the pool for meta-analysis, would allow the Agency to update its guidance in a more timely and transparent manner. (After a working protocol was put in place, it then could be modified over time to match changes in the Agency's general mortality risk valuation approach and meta-analysis methods, as necessary. See charge question 8.) Does the committee believe that developing such a protocol is feasible and desirable? Please explain.

The SAB believes that the Agency should establish a regular schedule for updating its value of risk reduction (VRR) estimates. The central-tendency estimate that the Agency currently uses is based on studies that are at least 20 and in some cases over 35 years old. Many of the studies included in the current pool may not satisfy the criteria for qualifying studies recommended by the Agency in the White Paper and further criteria recommended by the SAB in response to charge question 4. Moreover, the current estimate does not take into consideration the wealth of new studies published over the last 20 years that make use of better techniques, better data, and that better reflect current conditions. To avoid using VRR estimates based on decades-old and possibly obsolete research in the future, the Agency should establish a protocol for updating regularly the estimates of the value of risk reduction that it uses in its work.

The protocol should include a procedure for updating all of the information needed to construct the value of risk reduction. This should include the following:

- Identification of recent additions to the literature on valuing risk reductions, particularly related to mortality risk, as well as studies that provide new estimates of the income elasticity of the value of risk reduction.
- Assessment of the quality of those studies and the estimates contained therein according to criteria established by the agency, as discussed above. Studies that do not meet these criteria should be excluded from consideration.
- The estimates of risk reduction gleaned from the set of qualified studies should be put into comparable real dollar terms using appropriate income elasticity and inflation adjustments.
- The procedure for combining estimates should be in line with the recommendations in response to charge questions 2, 6 and 8.
- All of these procedures should be adaptable to take account of new information and the
 results of new research that might enable the Agency to employ a new methodology for
 updating its VRR estimates, such as through developing and parameterizing a structural
 benefit transfer model.

Updates of the Agency's estimates should be performed on a regular schedule in order to take advantage of new research as it becomes available. The exact timing of these updates will depend on the supply of new studies, the availability of Agency resources to devote to the task, and the nature of the review process for new estimates that the agency develops. The supply of research on valuing risk reductions has been growing in recent years as has the pace with which new studies are appearing and the Agency can have some influence on that supply through its research funding activities. While the supply of new research on this topic may be growing sufficiently fast to warrant annual updates of the VRR estimate, the requirements for review of new estimates produced by the Agency by the Scientific Advisory Board

may make it desirable from the Agency's perspective to update on a less frequent basis, say every 2 or 3 years, or even 5 years at the outside. All of these update schedules are a vast improvement over prior practice.

Regular updates of the value of risk reduction will require an education process to make legislators, administration officials, and the general public aware that estimates of the values of risk reductions are not static. They can be expected to evolve over time as data are improved and methods are refined. Change in the terminology used should assist in this regard, but in conjunction with its efforts to educate the public about the change in terminology, EPA should also take care to inform people about its plans for updating these values and provide information on why this is necessary and important.

4.8. Question 8 – Benefit Function Transfer Approach

In addition to the short-term issues that underlie charge questions 1-7, we are interested in supporting and conducting additional research to further develop EPA's health risk valuation methods over the longer-term. In particular, we would like to begin the transition from the point value transfer approach to a benefit function transfer approach. With this longer-term research and guidance development objective in mind, please answer the following questions:

a. Should EPA continue to use its current approach—that is, a point value or range of values, possibly with an adjustment for cancer risks—or is there now a sufficient body of empirical research to support the development of a more detailed form of functional benefit transfer?

As described above, the SAB recommends that EPA work toward developing a set of estimates of VRR for policy-relevant contexts (defined by risk and population characteristics), together with appropriate characterization of uncertainty about these estimates. The body of empirical research is clearly sufficient to estimate values for occupational accidents and may allow estimation of VRR for some other contexts (e.g., certain types of cancer and of respiratory or heart disease). VRR can also be distinguished by income and perhaps some other individual characteristics. Given the need for VRRs that differ by context, EPA's Science to Achieve Results (STAR) program could be used to fill this research gap.

b. If a functional transfer approach is feasible given the existing body of empirical results, should this be based on a meta-analysis or a calibrated structural preference function or perhaps some hybrid of these?

Alternative methods for characterizing the distribution of VRR and how it varies with risk and individual characteristics are discussed above (in response to charge question 2). The SAB recommends that EPA attempt to apply some of these approaches and evaluate the quality of the results for consistency with VRR estimates in particular contexts and for the plausibility of the pattern of results across contexts.

Moving toward a structural preference function appears to be desirable. It would provide an integrated, consistent framework for understanding how individuals trade off risks against consumption and income. By doing so, it would provide a stronger theoretical foundation for the benefit transfer task commonly faced by EPA: using data on relatively well-studied risks, such as sudden accidental death, to infer willingness to pay for reductions in other risks. Moreover, as noted by Smith et al. (2006), a structural approach may allow additional data on other aspects of individual choice to be brought to bear

on the problem. It may also provide a rigorous means for incorporating the results of risk-tradeoff studies which provide valuable information but are difficult to include in traditional calculations of willingness to pay for risk abatement.

Although a structural approach would provide many benefits, additional research is needed. For example, the existing literature has used a small number of restrictive functional forms. Before the structural approach will be ready for routine use, the effect of these restrictions must be investigated and the restrictions relaxed where possible. EPA should regard the structural approach as a high priority for research and an important long-term goal, but not yet as a replacement for traditional methods.

c. If the body of empirical literature is sufficient to estimate or calibrate some form of structural preference function, what are the key variables that should be included in such a function? That is, based on a priori theoretical considerations and previous empirical findings, which attributes of the affected individuals and the policy scenario should be included? What specifications are feasible given data availability?

As noted above, the theoretical and empirical literature on the structural approach is promising, but still at an early stage of development. The literature is not yet sufficient to estimate an authoritative model. As a research matter, a key initial consideration will be whether to formulate the model in terms of the attributes of risk (latency, morbidity, dread, etc.) or in terms of specific risks (cancer, heart disease). The former approach would be more versatile but the latter approach is likely to be more tractable in the short run. In research currently under review, for example, Cameron, DeShazo and Johnson (2010b) use both types of controls. Their stated preference conjoint choice study includes both the nature of the illness profile corresponding to a particular named health risk and the respondent's assessment of their personal subjective risk of the illness in question as well as their subjective impressions of the controllability of that type of risk.

d. Have the econometric issues we identified (unobserved heterogeneity, heteroskedasticity, and small sample size) been adequately addressed by the recent meta-analyses reviewed in Sections 4.1.1 and 4.2.3? Would the classical approaches that we suggest for overcoming these data limitations improve upon previous work? If a new meta-analysis is conducted, what statistical approach(es) would be preferred?

The econometric techniques that should be used in a meta-analysis will depend on the number of VRR estimates to be drawn from each study and the total number of observations available in the meta-analysis. For example, to be feasible, fixed effects estimators require a sufficient number of observations from each study. Random effects estimators assume that covariates in the model are uncorrelated with the error term, which may be reasonable under some circumstances but not others.

e. What role, if any, does the Committee believe that the life-cycle consumption and mortality risk framework could play in evaluating health risk reductions? In particular, does the Committee believe that this framework could be used as a foundation for some form of structural benefit transfer function?

A life-cycle consumption model can be particularly useful for helping to understand how individuals value risk reductions at different stages of the life-cycle, which is applicable to valuing risks that are

most prevalent for different ages and for evaluating effects of latency. Results of life-cycle models can be highly sensitive to parameters such as discount rates. Using data from stated preference and hedonic wage studies to parameterize a life-cycle model is an ambitious task. It faces all of the difficulties noted above for structural preference approach but in an even more complex form. Allowing utility functions to be age-dependent and to depend on risk characteristics in a manner that varies with age will be difficult. It is also true that the standard life-cycle model assumes people are expected utility maximizers, which may not be a valid assumption. Before pursuing this approach EPA should evaluate the literature that has estimated life cycle models for the purpose of understanding savings and retirement decisions. An important question is how well these models have worked in that context.

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APPENDIX A: EPA'S CHARGE TO THE SAB

MEMORANDUM

To: Holly St

Holly Stallworth, DFO

Science Advisory Board Staff Office

From:

Nathalie B. Simon, Associate Director

National Center for Environmental Economics

Date:

December 16, 2010

Subject:

Charge Questions for SAB-EEAC January 2011 meeting

The purpose of this memorandum is to transmit charge questions for consideration by the Science Advisory Board's Environmental Economics Advisory Committee (SAB-EEAC) during our upcoming consultation scheduled on January 20 and 21, 2011.

EPA and other agencies use a variety of tools, including benefit-cost analysis, to help inform regulatory and other public policy decisions that affect human health. When considering new regulations to reduce people's exposure to pollutants, EPA first estimates how much the various options would reduce mortality risks. EPA then calculates the benefits associated with those options by using published estimates of how much people are willing to pay for small reductions in their annual risks of dying. This estimate is commonly known as the "Value of Statistical Life" (VSL), but it is important to understand that this quantity does not measure the value of an individual life. Rather, the VSL is the total willingness to pay for small risk reductions summed over a large number of people. This estimate, together with other benefits of the regulation, are then compared to the costs.

EPA is now in the process of updating its guidance for conducting benefit-cost analysis, and has identified a number of important issues that should be considered. These are detailed in a white paper on "Valuing Mortality Risk Reductions in Environmental Policy," which will be submitted to the EPA's independent Science Advisory Board shortly for review and advice. The charge questions follow from a white paper submitted to the SAB-EEAC for review entitled "Mortality Risk Valuation for Environmental Policy." The paper addresses the following key issues:

- Terminology: Replacing the term "Value of Statistical Life," which has often been
 misunderstood as a measure of the value of individual lives, with the term "Value of Mortality
 Risk Reductions" (VMR). This change in terminology should help to avoid some of the
 confusion surrounding the interpretation of the VSL. It would not affect the results of the
 analysis itself, but rather how the benefits of reduced risks are reported and described.
- Cancer Differential: Taking into account potential differences in how much people would pay for reductions in their chances of dying from cancer relative to other causes when estimating the benefits of policies that reduce exposure to cancer-causing pollutants.

• Altruistic Effects: Taking into account that the amount of money people would pay for "public" risk reductions that affect everyone (like reductions in water pollution) may differ from what they would be willing to pay for "private" risk reductions that only affect the individual (say, choosing to install a water filter in your home). Many of the published estimates of willingness to pay are for private risk reductions, but since EPA regulations generally result in "public" risk reductions, accounting for these differences when estimating benefits could be important.

As indicated in the accompanying materials, advice on these issues will not only be important ultimately to the revision of our *Guidelines for Preparing Economic Analyses*, it will be of immediate relevance to the Agency in its pursuit of improved guidance on mortality risk valuation in particular. We look forward to the SAB-EEAC's review.

Please contact me if you have any questions about the attached charge.

Attachment

Cc: Al McGartland

Valuing Mortality Risk Reductions for Environmental Policy

1. Current EPA guidelines and standard practice use "Value of Statistical Life" (VSL) as the metric for valuing mortality risks. Section 3.1 of the white paper discusses the VSL terminology commonly used in mortality risk valuation exercises in greater detail. The white paper suggests that the Agency move away from using the traditional VSL terminology in favor of a new term of art for estimates of the marginal rate of substitution between health risks and income (see section 3.1). Specifically, the white paper suggests that the Agency refer to these estimates as the "value of mortality risk," and report the associated units using standard metric prefixes to indicate the size of the risk change, e.g., \$/mr/person/yr (dollars per milli[10⁻³]-risk per person per year), or \$/μr/person/yr (dollars per micro[10⁻⁶]-risk per person per year), etc. Does the Committee agree that the Agency should pursue such a change? Does the Committee believe that making these changes would ease or exacerbate the misunderstandings documented by Cameron (2010)? Would some other terminology or approach be preferable? Please explain.

Experts generally agree that *value function transfers* can outperform *point value transfers* in cases where the characteristics of the risks and/or the exposed populations differ between the source studies and the policy context in measurable ways. That is, the more commodity- and individual-specific attributes that can be included in the benefit transfer exercise, the better the estimate of willingness to pay. Charge questions 2 and 3 inquire about whether applications of benefits transfer methods to value mortality risk reductions from environmental pollutants can be improved by controlling for more of the attributes that distinguish the source studies from the policy scenario.

- 2. The white paper concludes that research since the 2000 EPA Guidelines suggests that people are willing to pay more for mortality risk reductions that involve cancer than for risk reductions from accidental injury (see section 3.3). Our preliminary review suggests that a "cancer differential" of up to 50% over immediate accidental or "generic" risk valuation estimates may be reasonable. Conceptually, would the weight of evidence (both theoretical and empirical) suggest there is a cancer differential? If so, does the Committee believe that our estimate of the differential is appropriate. If not, how does the Committee recommend the Agency incorporate cancer differentials in benefits analysis involving reduced cancer risks?
- 3. Environmental policies generally provide public risk reductions. However, research, particularly stated preference research, provides willingness to pay estimates for both public risk reductions as well as private risk reductions. And, some research indicates that individuals' willingness to pay for public risk reductions may be different than that for private risk reductions. One factor that may contribute to these differences is altruism, which, all else equal, should make values for public risk reductions larger than those for private risk reductions.
 - a. Should EPA rely on studies that estimate willingness to pay for both public and private risk reductions? If so, is it sufficient to control for this key characteristic in the modeling framework? Or, should EPA limit the analysis to studies according to the type of risk reduction in the study? If using only one type of study is recommended, should EPA use studies that estimate public or private risk reductions? If we are to limit the studies used to one type, is there a role for the excluded group?
 - b. Studies that estimate willingness to pay for public risk reductions may allow EPA to better capture altruistic preferences in benefit-cost analysis. Did the white paper adequately capture

the theory on how to incorporate altruism into the value of mortality risk reduction? How should altruistic preferences be treated in benefit-cost analysis? Should the Agency incorporate altruism into the value of mortality risk reductions, even if we are unable to distinguish the specific form of altruism involved (i.e., paternalistic or non-paternalistic)? More generally, what alternatives should the Agency pursue in the short-term to appropriately account for altruistic preferences when evaluating public programs, if any?

- 4. The two primary literatures used to assess willingness to pay for mortality risk reductions are stated preference studies and hedonic wage studies. The white paper assembles two databases summarizing studies in both literatures, capturing much of the information outlined in number 3 of the SAB-EEAC's recommendations dated October 2007 (see section 4). These studies, or a subset thereof, would form the basis of revised guidance in the near term as well as possible future meta-analyses.
 - a. The selection criteria employed in creating the two data sets are carefully outlined in the paper (see sections 4.1.2 and 4.2.4). Please consider these criteria in answering the following questions:
 - i. Should additional criteria be added to screen studies for inclusion in the datasets? If so, please specify those criteria. Should any criteria be eliminated or modified?
 - sii. Section 4.2.2 of the white paper discusses problems of measurement error associated with some common sources of occupational risk information among other concerns with the hedonic wage approach. Should EPA limit its selection of hedonic wage studies by the source of occupational risk information? For instance, studies relying on data from the Society of Actuaries (SOA) have been omitted from the described data set. Should the SOA studies be excluded? Should other sources be excluded as well?
 - b. Should any of the studies included in the datasets be eliminated? If so, please specify those studies and the reasons for eliminating them.
 - c. Is the committee aware of relevant empirical studies in the stated preference and hedonic wage literatures that are not adequately captured in this review? If so, please provide citations.
- 5. Income elasticities are discussed briefly in section 5 of the white paper. In keeping with Agency practice, we created the two databases by adjusting all estimates for income growth over time using an income elasticity value of 0.5 based on prior Agency reviews of the literature and results Viscusi and Aldy, 2003. In addition, we adjusted all estimates for inflation as well as for purchasing power parity where necessary, as recommended by the EEAC's October 2007 report. Does the Committee agree with this approach to accounting for income growth over time? Does the Committee believe the Agency should adjust its value of income elasticity for use in policy analysis in light of recent findings in the literature? If so, what value or range of values does the Committee believe should be used?
- 6. The white paper describes a simplified approach for updating the Agency's recommended mortality risk value estimate(s) (see section 5.1.1). This approach involves fitting a parametric distribution to the set of estimates from selected studies. This is similar to the approach used for EPA's current default VSL estimate.

⁶ The recommendations included specific features of hedonic wage and stated preference studies that should be identified in the studies.

- a. Should EPA pursue this approach for updating its mortality risk valuation guidance in the near term (until a more detailed analysis can be conducted)?
- b. If so, should the databases on which values are based be created using only one estimate drawn from each study or multiple estimates from each study?
- c. If only one estimate per study should be used, what criteria should the Agency apply in selecting the appropriate estimate? How would these criteria vary from one segment of the literature to the other? The paper describes the methods used to select independent estimates from each study. Does the Committee agree with the methods used?
- d. How important is it that estimates be drawn from non-overlapping subsamples? If multiple estimates per study are recommended in the construction of the meta-datasets, should the estimates be selected to avoid overlapping sub-samples?
- e. Does the Committee still favor analyzing the stated preference and hedonic wage estimates separately? If so, how should the separate results of these analyses be used in evaluating new policies? If not, how should they be combined in a single analysis?
- f. Would the Committee support the development and application of separate means or ranges generated from the two segments of the literature? Given separate means and/or ranges from each segment, should the results be weighted and combined to produce a single point estimate or range? If so, how? Are other presentations of the results preferable? More generally, how should uncertainty in the estimated value(s) of mortality risk reductions be handled in benefits analyses?
- 7. We are interested in developing a standardized protocol for updating the Agency's recommended mortality risk value estimates on a regular basis—for example, every 5 years or so—to incorporate new estimates from relevant economic valuation studies as they appear in the literature. Such a protocol might be based on the approach outlined in Section 5.1.1 or something similar. This approach, combined with a set of rigorous criteria for determining which new studies and value estimates are suitable for inclusion in the pool for meta-analysis, would allow the Agency to update its guidance in a more timely and transparent manner. (After a working protocol was put in place, it then could be modified over time to match changes in the Agency's general mortality risk valuation approach and meta-analysis methods, as necessary. See charge question 8.) Does the committee believe that developing such a protocol is feasible and desirable? Please explain.
- 8. In addition to the short-term issues that underlie charge questions 1-7, we are interested in supporting and conducting additional research to further develop EPA's health risk valuation methods over the longer-term. In particular, we would like to begin the transition from the point value transfer approach to a benefit function transfer approach. With this longer-term research and guidance development objective in mind, please answer the following questions:
 - a. Should EPA continue to use its current approach—that is, a point value or range of values, possibly with an adjustment for cancer risks—or is there now a sufficient body of empirical research to support the development of a more detailed form of functional benefit transfer?

- b. If a functional transfer approach is feasible given the existing body of empirical results, should this be based on a meta-analysis or a calibrated structural preference function or perhaps some hybrid of these?
- c. If the body of empirical literature is sufficient to estimate or calibrate some form of structural preference function, what are the key variables that should be included in such a function? That is, based on a priori theoretical considerations and previous empirical findings, which attributes of the affected individuals and the policy scenario should be included? What specifications are feasible given data availability?
- d. Have the econometric issues we identified (unobserved heterogeneity, heteroskedasticity, and small sample size) been adequately addressed by the recent meta-analyses reviewed in Sections 4.1.1 and 4.2.3? Would the classical approaches that we suggest for overcoming these data limitations improve upon previous work? If a new meta-analysis is conducted, what statistical approach(es) would be preferred?
- e. What role, if any, does the Committee believe that the life-cycle consumption and mortality risk framework could play in evaluating health risk reductions? In particular, does the Committee believe that this framework could be used as a foundation for some form of structural benefit transfer function?

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

Docket No. FDA-2011-N-0921

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy, Planning, and Legislation
Office of the Commissioner

Executive Summary

The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The rule addresses microbiological risks from certain routes of contamination, including workers, agricultural water, biological soil amendments of animal origin, buildings, tools and equipment and sanitation, and wild and domesticated animals. The rule also includes specific requirements for sprouts. Using a science-based framework, we characterized the public health risks associated with the consumption of produce and are establishing specific provisions that address the risks of microbial contamination from these routes of contamination. The primary benefits of the provisions in this rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first ten years after the effective date of this final rule at seven percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at three percent), valued at \$925 million annually (\$976 million at three percent). Similarly, annualized costs, estimated at seven percent, are expected to be approximately \$366 million annually (\$387 million at three percent). Additionally, annualized costs for foreign farms are estimated to be approximately \$138 million annualized at seven percent (\$146 million at three percent).

Table of Contents	
I. Introduction and Summary	3
A. Introduction	3
B. Summary of Costs and Benefits	4
C. Comments on the Preliminary Regulatory Impact Analysis and Our Respo	onses 5
II. Final Regulatory Impact Analysis	
A. Background	
B. Need for Regulation	34
C. Purpose of the Rule	36
D. Inputs and Assumptions	36
E. Benefits of the Rule	48
F. Costs of the Rule	
1. Personnel and Training (Subpart C)	63
2. Health and Hygiene (Subpart D)	64
3. Agricultural Water (Subpart E)	
4. Biological Soil Amendments (Subpart F)	75
5. Domesticated and Wild Animals (Subpart I)	
6. Growing, Harvesting, Packing, and Holding Activities (Subpart K)	77
7. Equipment, Tools, Buildings, and Sanitation (Subpart L)	
8. Sprouts (Subpart M)	79
9. Recordkeeping (Subpart O)	
10. Administrative Provisions	
11. Corrective Steps	99
12. Variances	
13. Summary of Costs	100
G. Distributional Effects	104
H. International Effects	
I. Uncertainty and Sensitivity Analysis	
J. Analysis of Regulatory Alternatives to the Rule	
III. Final Small Entity Analysis	
A. Description and Number of Affected Small Entities	
B. Description of the Potential Impacts of the Rule on Small Entities	
C. Alternatives to Minimize the Burden on Small Entities	118
IV References	120

I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule *will* be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule *will* have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$141 million, using the most

current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA *does* expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Costs and Benefits

The requirements of the final Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (Produce Safety rule, the final rule, or the rule) will lead to higher costs for both the industry and consumers than the current state of no new regulatory action. As described in the preamble, the final rule includes requirements for covered domestic and foreign farms engaged in the growing, harvesting, packing, and/or holding of one or more raw agricultural commodities (RACs) that are covered produce. The final rule also requires covered domestic and foreign farms to train their employees; take certain measures related to employees' health and hygiene; monitor, understand, and take certain measures related to their agricultural water; assess for domesticated and wild animals activity in areas used for covered activities; take certain measures during growing, harvesting, packing, and holding activities; and take certain measures relating to sanitation, including cleaning and sanitizing equipment and tools, and appropriately maintaining buildings. In addition, the rule establishes certain requirements for the growing, harvesting, packing, and holding of sprouts. Farms will be required, to take appropriate corrective actions, and maintain certain records, including records that document these corrective actions. The affected farms will incur costs to comply with this final regulation. Depending on how the farms

¹ When discussing Raw Agricultural Commodities (RAC), we refer to RACs covered by the rule unless otherwise noted.

in the affected markets respond to these requirements, some of the costs may ultimately be borne by consumers as prices rise. The higher prices, however, will likely not be sufficient to fully offset the costs borne by farms.

Table 1 summarizes the costs and benefits of the Produce Rule. More detail on these estimates is provided in the relevant sections of this document, specifically benefits come from Table 6 and costs come from Table 37.

Table 1: Summary of Benefits and Costs of Final Rule (in millions)

	Discount Rate	Primary Estimate	Low Estimate	High Estimate
Annualized Benefits over 10 years	3%	\$976	\$748	\$1,195
	7%	\$925	\$710	\$1,132
NPV of Benefits over 10 years	3%	\$8,322	\$6,381	\$10,190
	7%	\$6,498	\$4,988	\$7,950
Annualized Costs over 10 years	3%	\$387	\$319	\$425
	7%	\$366	\$301	\$401
NPV of Costs over 10 years	3%	\$3,304	\$2,717	\$3,624
	7%	\$2,571	\$2,113	\$2,817

In addition to the costs presented in Table 1, we estimate there will also be costs incurred by foreign farms shipping RACs to the U.S. We estimate a total annualized cost to foreign farms shipping produce RACs to the US of \$136 million annually, using a 7 percent discount rate (\$146 million using a 3 percent discount rate).

C. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

FDA's proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (78 FR 3504; the 2013 proposed rule) was

published on January 16, 2013 and its comment period ended November 22, 2013. In addition, we published a supplemental notice to the proposed rule on September 29, 2014 (79 FR 58434) and its comment period ended December 15, 2014. (We refer to both of these documents collectively as "the proposed produce safety rule.") We prepared a full "Preliminary Regulatory Impact Analysis" in connection with the proposed and supplemental rule. We also included sections titled "Costs and Benefits" and "Initial Regulatory Flexibility Analysis" in the preamble to the proposed rule (76 FR 19192 at 19220-19225). In the following paragraphs, we describe and respond to the comments we received on our analyses of the impacts presented in those sections. We have numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

Comment 1) Several commenters express concern about the magnitude of the cost of the rule. Specifically, they state that the rule would: cost farmers over half of their profits; put an unfair financial burden on small and medium farms; cause many farms to go out of business; deny farmers access to local food markets by making it harder to diversify (e.g., a small strawberry operation that is part of a large non-produce farm may be subject to the rule even if the specific sales of strawberries are below the exemption cutoff); and prevent new farmers from starting to farm.

Response 1) FDA recognizes that the cost of this rulemaking is not inconsequential. However, we believe the need for a safer food supply warrants such expenditures. In our analyses, we find that the average cost of the rule for very small farms is \$2,885 per farm, while the average value of produce sales is \$85,616. Similarly,

we find the average cost for small farms is \$15,265 per farm, while the average value of produce sales is \$358,814 per farm. We do not believe that this rule will in any way hinder farmers' access to local markets. In fact, exemptions are set up in such a way as to encourage sales of produce locally (Ref. 1). We have revised our provisions related to coverage of the rule (see 112.4, which establishes the monetary threshold based on sales of produce (rather than sales of food)), and the rule, as finalized, will not hinder the diversity or force those farms that have a relatively small amount of produce grown on their farm to exit the industry. Finally, we recognize that these costs will affect farmers entering into the industry, but we believe that all new farmers should be practicing safe food practices, especially in the cases where the produce is likely to be consumed raw. See also section III of the rule.

Comment 2) Several commenters state that the proposed produce safety rule will have additional health costs because, by being disadvantageous to small and local farms, they will reduce access to fresh, local, and healthy food. Commenters also suggest that FDA needs to consider large scale crop losses, harm to soil and the municipal water supply, and ecological impacts brought on by the water testing requirements, in its cost analyses.

Response 2) FDA does not believe that this rule will reduce access to produce. In fact, exemptions are set up in such a way as to encourage sales of produce locally (Ref. 1). Additionally, FDA has conducted an assessment of impacts of the rule on the human environment of the United States, and prepared an environmental impact statement (Ref. 2). According to the EIS, "providing that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements should not result in significant environmental impacts to vegetation, wildlife, and wetland resources. However, such

applications may result in short-term minimal to moderate impacts on these resources particularly if applied preceding substantial periods of precipitation which may increase runoff. Such impacts would be intermittent and acute." It further states that "if approved products are used in accordance with labeling requirements, chemical contamination is not expected to pose a human health risk." In terms of soil, the EIS states, "...chloride is not adsorbed by soils and moves readily with the soil-water; is taken up by the crop; moves in the transpiration stream; and accumulates in the leaves. The chemical reactions that occur when chlorine and organic matter are exposed to each other also produce toxic and carcinogenic by-products. The use of antimicrobials, however, would not be expected to exceed the threshold that would be toxic to crops, as long as labeling requirements are followed for application purposes, and adverse effects to crops from overexposure to chemical treatments should not occur."

Comment 3) Several commenters state that the water testing requirements will be overly costly to farms using water from creeks, streams and rivers,.

Response 3) We acknowledge that there is a cost to testing water; however, we believe that the testing is important given the significant risk of foodborne illnesses presented by agricultural water as a potential route of contamination. Numerous changes have been made to make the requirements for agricultural water more flexible (see section XIII of the rule) and we have attempted to account for those flexibilities within this analysis. In total we estimate that agricultural water provisions, as written in the final rule, will cost approximately \$37 million dollars annually, which represents an average cost to a single farm of approximately \$1,058 per year.

Comment 4) One comment states that FDA did not compare less costly alternatives, such as establishing labeling requirements to instruct consumers to wash produce.

Response 4) We believe that such an approach would be ineffective at reducing the human health burden associated with contaminated produce, and therefore we did not analyze the cost of such an approach. There are already a number of education campaigns currently in progress, or that have been completed, which try to stress safe food handling practices to the consumer. However, these are not completely effective in reducing foodborne illness. We also note that establishing new labeling requirements does have the potential to involve significant costs, especially where no label is currently required, such as for many produce RACs.

Comment 5) Several commenters state that the costs of water testing are particularly burdensome for operations with multiple water sources.

Response 5) The water testing provisions have been revised. The most burdensome testing regimen is associated with the use of untreated surface water that is used during growing of covered produce (other than sprouts) using a direct water application method. If farms use untreated surface water source(s) for this purpose, they will generally need to perform, for each source, an initial survey of 20 samples and recurring annual samples of five per year, which is estimated to cost approximately \$692 annualized over 10 years. The rule includes a provision allowing sharing of water testing data under certain circumstances (§ 112.47(a)(2)). This will allow some farms to reduce testing costs by sharing testing data.

Comment 6) Several commenters state that customers may require partial or full compliance with the produce rule standards even for operations that may be otherwise exempt, therefore causing these operations to incur the costs of the produce rule.

Response 6) FDA recognizes that some costs may potentially be incurred by farms not covered by this rule that are not required by FDA. To our knowledge, however, there is no data on which to base a reasonable estimate of these costs not directly attributable to the rule. Uncovered farms that incur these costs likely do so in order to maintain market share and thus maximize revenues. We include the costs for farms not covered or otherwise exempt for maintaining paperwork related to certain produce exempt from the Produce Safety rule, and costs of complying with modified requirements for those farms eligible for a qualified exemption with modified requirements. Anything done by a farm to comply with aspects of the rule from which they are officially exempt would likely be performed to preserve market share and/or profitability.

Comment 7) Several commenters state that the FDA should not assume small and very small farms only operate three months out of the year, and that large farms operate only 6 months per year and harvest, pack or hold produce only 90 days. Some suggest increasing season estimates for all farms depending on the region.

Response 7) We agree that the original time estimates for very small, small, and large farms may have been underestimated for some farms. Therefore, we have increased our estimates of operating days for very small farms to 100, small farms to 150, and large farms to 200. This is not to say that these farms do not carry on operations year round, but, for our costs analysis, we are primarily concerned with those times when the harvested or harvestable portions of the produce are exposed on the farm. Additionally,

because we do not explicitly examine farms by region, but are tasked with the average costs to all farms operating within the US, applying regional differences to operations is not possible for this analysis.

Comment 8) Several commenters state that FDA should include costs for farm mixed-type facilities in their cost-benefit analyses.

Response 8) We currently estimate the cost to all farms that meet the current farm definition. The analysis of the costs and benefits of the produce rule is not affected by whether or not a covered farm is also a facility subject to the Preventive Controls for Human Food (PCHF) Rule. If a farm is covered under the produce rule, then it must adhere to the rule. If that farm is also a facility subject to the PCHF rule, then the costs it incurs by adhering to the PCHF rule will be accounted for in the cost and benefit analysis of the PCHF rule (Ref. 3).

Comment 9) Several commenters state that FDA should analyze how the costs of the rules will be passed on to consumers (e.g., via increased prices).

Response 9) FDA estimates the costs to industry and society as a whole but does not estimate who will actually incur those costs (e.g., farms, intermediaries, retail establishments, or end consumers). This is largely due to the lack of quantifiable data on the issue. However, the total costs of this rule (\$560 million, as shown in Table 34) when fully implemented represent approximately 1.5 percent of the total value of produce sold in the US (\$38 billion). Additionally, the total cost to foreign farms that ship to the US is \$211 million (as estimated in Section H, International Effects), once the rule is fully in effect, meaning that the total cost of this rule, foreign and domestic, represents approximately 2 percent of the total value of the US produce market. This means that

even if the total costs of compliance were passed on to consumers, which are highly unlikely, it would represent a price increase of only 2 percent.

Comment 10) Several commenters state that "FDA disguises the first-year costs of the regulations by annualizing them over 7 years for depreciation," which "ignores the issue of whether the farmer has the money to comply in the first year to begin with, as well as the fact that many small farmers do not have sufficient income to make depreciation cycles relevant."

Response 10) FDA annualizes cost in accordance with Circular A-4 and Executive Order 12866 (Ref. 4;5). This is not to 'disguise' the costs, but rather to illustrate the likely costs of financing larger purchases over the long term. However, to illustrate the complete first year costs, not annualized over any time horizon, we also present these costs in Table 34. Summary of Costs for the Produce Safety Rule (in millions)

Comment 11) One commenter states that FDA's estimated rental value of \$359 per acre for a full year is too small.

Response 11) This estimate was based on the best data that we could find on crop land values for the proposed rule. However, because certain requirements related to biological soil amendments of animal origin have been removed from the final rule, related costs estimates have also been removed from this analysis and the rental value of land no longer enters any of our calculations of costs to a farm.

Comment 12) One commenter states that there are not any EPA approved water treatments, and that farmers would either have to stop irrigating (which will lead to crop damage) or turn to public water sources, which can be more expensive. Another

comment adds that the "cost required to invest in a groundwater pump can be significant and initial costs can be substantial. In 2013, in many parts of the West, drilling and developing a new groundwater irrigation well costs between \$100,000 and \$500,000 to supply water to 120 acres of productive farm land"

Response 12) As discussed in section XIII of the final rule, in § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44(a) or (b), and treatment is only one of those options. We anticipate that covered farms will consider and implement the flexible options provided in §§ 112.45(a) and (b) and 112.49, as appropriate, prior to or in conjunction with considering whether to treat water to ensure that it meets the applicable requirements for its intended use. Indeed, we believe some of these options are likely to be more feasible than the option to treat water. Moreover, covered farms will have two additional years (beyond the date of compliance for the remainder of the rule) to comply with many of the water provisions of this rule for covered activities involving covered produce (except sprouts), which is intended to help farms to consider and implement measures that are most appropriate for their operations.

Comment 13) Several commenters state that the Clean Water Act statistics do not provide a good estimate of how much irrigation water would fail to meet the EPA recreational water standard. They state that there is no information in the report about which of the water sources that don't meet the standards are used for irrigation, how much irrigation water is drawn from impaired sources, and groundwater usage.

Response 13) We agree that EPA's Clean Water Act statistics do not provide precisely the measurements we would prefer to estimate the amount of water that is likely to fail to meet the microbial water quality criteria in § 112.44(b); however, in the absence of another source, we believe this to be the most comprehensive and nationally representative source of data available. Because commenters did not provide any additional data or sources of data on this topic, and because we were unable to find any new or additional sources, we retain this as our source for estimates of water quality in the final analysis.

Comment 14) Several commenters state that there is no analysis of the cost of imposing microbial water quality criteria.

Response 14) The costs of imposing microbial water quality criteria are realized through treatment of water used in growing or post-harvest activities (an estimate affected by the number of farms we estimate that will be able to use other methods to meet the microbial water quality criteria, such as reinspection/correction and reliance on die-off or removal rates). These costs are presented in Table 18 and Table 19 of the analysis.

Comment 15) Several commenters argue with FDA's cost analysis by providing counterexamples, which primarily referred to one farm, one specific region, or one specific crop.

Response 15) For a national analysis of the costs and benefits of this rule we are not able to comprehensively account for farms by commodities or agricultural region. We are aware that there are differences in needs and resources across different farms, and as such we attempt to provide a national average estimate that reflects this variety.

Commodities and regions of production are taken into account when constructing our costs estimates whenever there are data which allow us to do so.

Comment 16) Several commenters state that FDA needs to account for travel and staff/lab time in the costs of water testing.

Response 16) We explicitly account for these costs in the original analysis. Table 43 estimates the 0.5 hours of farm labor and 1 hour of laboratory travel time labor per sample (Ref. 6) This represented a total cost of a single water test of \$87.30; for the final analysis we have increased this estimate to \$110 per sample. The hourly estimate is retained in the final analysis; however, wage rates have changed from those presented in the PRIA.

Comment 17) One commenter states that FDA underestimates the costs associated with subpart E (Agricultural Water), and offers their own estimation, which states that the minimum cost for compliance with the rule, including testing and the associated, time, labor and other incurred costs, would be \$7,912 for a single surface water supply source (regardless of farm size). They state that FDA's initial economic estimate for a very small farm was \$4,697, which was less than 60 percent of the cost they estimated.

Response 17) We have re-evaluated the costs associated with Subpart E, Agricultural Water. Our final estimate indicates that water testing will cost an average of \$1,058 per year. While this is somewhat below the commenter's average costs, we believe it represents the most accurate estimate utilizing the most recent and applicable data sources.

Comment 18) Several commenters express concern that the costs of water testing requirements will fall disproportionately on small farmers and farms in remote areas. For

example, it may be more costly for a single-operator farm to spend time on testing.

Farms in remote areas may have trouble accessing a lab, and may need to pay extra expenses to ship samples to far away labs.

Response 18) We include the cost of shipping samples to labs when one is not nearby. We then average the costs of a local laboratory sample and shipped sample together to produce one average cost of laboratory testing across farms. The original estimate was provided in Table 43 of the PRIA (Ref. 6;7) and is retained here in the final analysis. See also section IV.G. of the final rule where we address comments about reducing burden on small farms.

Comment 19) One commenter states that this rule "will impose substantial economic burdens upon American citizens which will not be imposed upon foreign producers. Consequently, foreign produce will be less expensive than produce grown in the United States."

Response 19) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage United States farms as compared to foreign farms.

With respect to enforcement, FDA intends to use the resources at its disposal to ensure that both domestic and foreign producers are following the requirements of the rule. As discussed in Subpart Q of the rule, our strategy to ensure the safety of produce, both domestically produced and originating from foreign farms, will focus on education, training, and guidance to achieve compliance. This will include outreach to foreign governments. We will also work to provide education and assistance in local languages to

reach farmers exporting covered produce into the United States, including by working with organizations and other sources of information that are familiar and accessible to the produce farming community (such as alliances, international organizations, universities, trade associations, foreign partners, Joint Institute of Food Safety And Nutrition, and federal agencies (such as United States Agency for International Development and United States Department of Agriculture), among others).

Inspections will also play a key role. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed, such as to prevent significant hazards from entering the food supply or in response to produce safety problems. While FDA is not in a position to inspect every foreign farm that produces food for consumption in the United States, the inspections FDA is able to conduct will be bolstered by other efforts, such as the final Foreign Supplier Verification Program rule establishing subpart L of 21 CFR part 1. The FSVP regulation establishes requirements for importers to verify that imported food (including produce) is produced in compliance with the produce safety regulation or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required in the United States.

Comment 20) One commenter references data from the USDA, which estimated that the average net farm income for farmers nationally was 10 percent of sales in 2011, and argues that the estimation implies that for a farm with less than \$250,000 in annual sales, complying with the Produce Safety rule requirements may consume more than half of their profits.

Response 20) We have found sources from the USDA that confirm the fact that, for many farms, farming is not the primary source of income (Ref. 8), and that, in general, roughly 90 percent of farm income comes from off farm sources (Ref. 9). However, these statistics refer to total farm income, while our cost estimates are based on sales of produce. We do not include any other farm income sources in our estimations of farms that are covered by this rulemaking; produce sales alone are what determines coverage throughout the analysis.

Comment 21) One comment suggests that FDA has not considered the fact that FSMA regulations are different from USDA GAP (or other third party) audits. Some suggest that FDA allow the use of GAP.

Response 21) See section IV.F. of the final rule where we address comments about existing industry guidelines and certification programs. Where requirements are different for farms already performing GAPs we have estimated the cost for a change in practice. However, if farms are already conducting the required activities through GAPs or some other agreement, we have attempted to remove previously incurred costs out of our analysis.

Comment 22) One comment states that FDA's cost analysis does not differentiate between costs across crops or across production regions.

Response 22) This is true. For a national analysis of the costs and benefits of this rule we are not able to differentiate farms by commodities or agricultural regions. We are aware that there are differences in needs and resources across different farms, and as such we attempt to provide a national average estimate that reflects this variety. Although, the costs are not differentiable by these factors both commodities and regions of production

are taken into account when constructing our costs estimates whenever there are data which allow us to do so.

Comment 23) One commenter states that FDA's estimates do not match with current average costs for the produce sector, and cite things such as "outdated wage rates and inconsistent application of wage rates throughout, and "a lack of cost estimates for replacing tools and equipment that were not able to be brought into compliance with FDA's proposed rule." Another commenter offers an alternative estimation based on more recent BLS data.

Response 23) In an attempt to more accurately reflect the true costs to farms, FDA has updated its wage rates to 2013 levels according to the BLS. Additionally, we now apply a one hundred percent overhead to all wages to more accurately account for the indirect costs of labor which may be incurred. The rule requires that certain tools/equipment must be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained, and requires keeping tools/equipment clean and in sanitary condition. We expect the replacement of tools/equipment as a result of this rule to be rare, however, as such requirements are sufficiently flexible to accommodate many types of equipment and tools.

Comment 24) A few commenters offer their own estimates of the costs of the produce rule. They state that these estimates are based in "more accurate and current data," and on their own independent research (e.g., interviews). Specifically, they assume that: 1) labor costs are higher, based on updating wage rates from 2000 to 2012; 2) average cost of water sampling is higher, based on a higher expected cost of analysis; 3) covered farms would test their water more frequently (weekly), based on a higher

expected frequency of irrigation; 4) large farms have two irrigation water distribution systems to inspect, based on the assumption that larger farms may have more irrigation facilities than smaller ones; 5) farm owners or managers are responsible for recordkeeping, due to potential liability issues; 6) record keeping hours are much longer, based on interviews with industry associations; and 7) the time per acre it takes to comply with the rule is higher, based on the fact that FDA's costs are calculated using an expected minimum that does not apply to all farms. Overall, these commenters state that FDA needs to perform a more detailed, crop-specific analysis, and not make generalizations for all products and regions. They also suggest that a sensitivity analysis could be beneficial.

Response 24) These analyses provide a number of suggestions for improving the analysis and we have incorporated changes where the data were nationally applicable and relevant. Additionally, we do provide a sensitivity analysis both in this document and in the original PRIA. In response to the individual suggestions: 1) we have updated wage rates to 2013, which more accurately reflects the costs that may be incurred by farmers today; 2) similar to the 25 percent increase in wage rates (from 50 percent overhead to 100 percent), we have increased the estimated cost of a single water test by approximately 25 percent; 3) the weekly testing frequency originally proposed for certain water sources and uses in the 2013 proposed rule have been removed from the final water testing requirements in favor of a tiered testing frequency that results in less frequent testing; therefore we do not estimate that any weekly water testing will occur; 4) we have doubled the time estimated for large farms to inspect their agricultural water systems; 5) while it is true that the owner, operator, or agent in charge of the farm will be responsible

for keeping records, we believe that the actual people creating the records will typically be the farm's workers; 6) while some records may take longer to produce from scratch, we believe, based on a study of industry recordkeeping practices from Economics Research Group (Ref. 7) that our estimated recordkeeping burden is close to accurate; and 7) we believe the time costs estimated throughout the document represent a reasonable average by estimated farm size. Finally, it should be noted that a crop by crop analysis was not feasible given the large number of individual crops covered and the nature of farms that grow multiple crops on the same acres; therefore, we believe our approach, estimating costs to the average covered farm based on inputs, is the most logical way to estimate compliance costs with this rule.

Comment 25) One commenter states that on page 6 of the report, the Farm Supervisor Mean Wage Rate is calculated as \$30.26 per hour, while in the section on agricultural water testing, a wage rate of \$30.83 per hour is used instead.

Response 25) We have simplified our analysis to incorporate only those wage rates discussed in section 2. Additionally we have updated wage rates to 2013, which more accurately reflects the costs that may be incurred by farmers today.

Comment 26) One commenter states that the probability of other significant events that could impact produce farms and create a need to prevent contamination from sewage is ignored. For example, the commenter notes hurricanes and tornadoes could both generate problems with sewage and septic systems, but the cost of monitoring after these events is not included.

Response 26) We agree that these events can have a significant impact on the actions a farm may take to prevent contamination of their produce. Our analysis of the

cost of the rule, however, takes into account average current farming practices. We are not able to estimate the probability of a natural disaster followed by the expected cost of contamination reduction.

Comment 27) According to one commenter, FDA assumes that it takes one minute to clean and sanitize one tool, and there is one tool per farm job, but sometimes more than one tool is used or it takes longer than 1 minute to clean the tool.

Response 27) For a national analysis of the costs and benefits of this rule, we are not able to differentiate our estimates based on individual cases (i.e., individual jobs). We are aware that there are differences in needs and resources across different jobs, and as such we attempt to provide a national average estimate that reflects this variety. While some tools may take longer to clean, others will take a much shorter time, and certain jobs may not even require a tool at all (e.g., harvesting by hand).

Comment 28) One commenter stated that feedback from several produce industry groups suggests that their crops would require additional irrigation beyond 0.77 acre feet per growing season, and that the amount of water needed from planting to harvest varies significantly by crop.

Response 28) In Table 49 of the original PRIA, we estimate that it takes approximately 2.16 acre/ft. of water to irrigate a single acre using direct water application techniques. Because this estimate comes directly from the 2008 Farm and Ranch Irrigation Survey (FRIS), we retain it in the final analysis (Ref. 10). Additionally, because we do not explicitly examine farms by crop, but are instead tasked with providing the average costs to all farms operating within the US, applying crop-based differences to operations is not possible for this analysis. Finally, our estimate is very

similar to that found by the U.S. Geological Survey, which states the national average application rate for irrigated water in 2005 was 2.35 acre-feet per acre (Ref. 11). This estimate is not preferred because it is not as current, but it provides further support for our retained estimate.

Comment 29) One commenter states that FDA's estimates of the number of not covered and exempt farms by sales class is difficult to verify and analyze because the data does not come from a publicly available source.

Response 29) We get our data to estimate the number of not covered and exempt farms from the National Agricultural Statistics Service's Census of Agriculture, which is publicly available. Summary tables are available at the Census of Agriculture's website (Ref. 12), which allow the public to see the data in summary format. Anyone can apply for access to the micro-data (Ref. 13), which will allow for a full, independent analysis. Due to data restrictions and disclosure concerns, we are not able to provide the full data set ourselves.

Comment 30) One commenter suggests that FDA should consider using a value of eight hours of additional training in food safety, which greatly increases the cost.

Response 30) Table 112 from the PRIA estimates that farm operators are involved in food safety training for a total of eight hours, seven in training and one additional for travel time. These time estimates are retained in the final analysis; however, wage rates have been updated to more accurately reflect the current state of the industry. We do not believe that it will be necessary to further train each worker for eight hours in food safety, once the manager/operator has received the more comprehensive training.

Comment 31) One commenter asks how FDA will determine if a farm is exempt.

Response 31) We are adding a new provision § 112.7 to establish certain recordkeeping requirements in relation to a qualified exemption. Records required under this provision will assist farms in determining whether they are eligible for a qualified exemption and will assist FDA in verifying eligibility.

Comment 32) Several commenters state that a specific type of produce (e.g., apples) has never been associated with food borne illness outbreaks, which means that, in the case of this type of produce, in the commenters' view, there are no benefits from the rule. Some suggest that FDA should look at comparative benefits by type of produce. Others say that grouping high and low risk commodities together in our analysis distorts the risk, and therefore the benefits estimation. In addition, several commenters state that a specific part of the rule (e.g., agricultural water testing) will provide no benefit.

Response 32) Although certain commodities have never been implicated in an outbreak during the time period analyzed, there are numerous outbreaks which occurred in association with produce commodities that had previously not been implicated in an outbreak. These cases are of great public health concern and failing to take into account the sporadic nature of foodborne illness may miss a large potential threat to public health. Table 8 provides a pathway specific breakdown of the implicated causes of outbreak illnesses. Additionally, the rule focuses on the potential routes of contamination of produce, and covers specific practices, procedures, and processes on a farm, all of which may present significant risk, regardless of the commodity grown, harvested, packed, or held at the farm. See discussion in section IV of the rule.

Comment 33) Several commenters state that FDA has not provided "real" evidence of a public benefit to this rule.

Response 33) The estimation of benefits are based on the most accurate and upto-date data on produce related foodborne illness. Additionally, the estimates of effectiveness are based on a number of studies, citing experts in produce related foodborne illness, which all point to these safety measures having a measureable effect on the number of produce related foodborne illness.

Comment 34) Many sources state that FDA hasn't done a cost-benefit analysis for the supplier program. Comments suggest that FDA doesn't present any information as to how that program will affect farms, especially those already affected by the produce rule.

Response 34) We interpret these comments to be referring to requirements of the PCHF and FSVP rules, not this produce safety rule. There are only a few specific requirements in this rule that relate to entities in a farm's supply chain other than the farm itself, and we do not consider any of these requirements to constitute a "supplier program." The relevant provisions are: § 112.2(b)(2) for produce eligible for exemption because it receives commercial processing to adequately reduce pathogens (requiring certain disclosures to, and written assurances from, a farm's customers related to such processing); § 112.60(b)(1) for treated biological soil amendments of animal origin received from third parties (requiring covered farms to keep certain documentation related to the third party's treatment and handling of such materials); § 112.142(b)(2) relating to seeds or beans used for sprouting that may be contaminated with a pathogen (requiring sprouting operations to report that information to seed/bean suppliers under certain circumstances); and §§ 112.142(e) and 112.150(b)(1) allowing sprouting operations to rely on prior treatment of seeds or beans for sprouting conducted by a grower, distributor, or supplier with appropriate documentation. The costs and benefits of

these provisions have been included in our analysis for this rule. The costs and benefits associated with the supplier programs in FDA's PCHF and FSVP regulations are discussed in the FRIAs related to those rules.

Comment 35) Many cite the benefits of diversification, and say FSMA should incentivize diversification, not discourage it. Similar comments are made about the benefits of organic food, rich top soil, etc.

Response 35) While FDA believes there may be benefits to the farmer and farmland of diversification of crops and organic farming, to our knowledge, there are no quantifiable impacts on the human health burden associated with produce from these two activities. Additionally, the primary goal of our integrated approach to this rule was to not single out any specific crop or to limit diversification of crops in any way. See section IV.I. of the rule.

Comment 36) One comment states that no real cost-benefit analysis has been done because we perform a qualitative risk analysis. This comment further suggests that we have not complied with Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives.

Response 36) The Qualitative Assessment of Risk (QAR) is only one piece of information that helped to inform both the rule and the quantified estimation of benefits. FDA believes that we have fulfilled all the requirements for a complete regulatory impact analysis required under the pertinent Executive Orders.

Comment 37) Several commenters suggest that FDA significantly overestimated the benefits of the proposed rule, and made "unjustified leaps of logic". Specifically, they state that applying Scallan's multiplier to estimate foodborne illness leads to an

overestimation of foodborne illnesses attributed to produce, and that our estimates were significantly higher than Scallan's (Ref. 31). They suggest that FDA's use of this multiplier is unjustified, and that we should look at more than one study. They also criticize FDA's use of a "shaky survey" to estimate the effectiveness of the rule, as well as the fact that FDA extrapolates to all produce some results based on the leafy greens and tomato industries, which are associated with the highest number of outbreaks.

Response 37) FDA does not believe that it has overestimated the benefits of this rule. We acknowledge that some assumptions were made when data were less than robust, specifically when estimating the 'unidentified' burden of illnesses. To alleviate this concern we provide a more conservative estimate, which reduces our estimated number of unidentified illnesses. To get this number, we multiply the total number of estimated preventable illnesses attributable to FDA regulated produce by 4 to obtain a number of unidentified illnesses which is consistent with Scallan, et al., who estimate that unidentified illnesses make up about 80% of all foodborne illnesses. Additionally, we only implicitly, not directly, apply Scallan et al.'s multiplier in the estimation of quantified benefits. We use only the annual incidence of foodborne illness by pathogen to compute the number of annual illnesses associated with produce, although this does implicitly have a pathogen multiplier that is estimated by Scallan using active and passive surveillance.

Comment 38) One commenter suggests that FDA has overestimated the benefits of the rule, and proposes omitting Fresh Cut produce from the benefits, as well as unidentified illnesses, which may be "too speculative." They offer their own estimates, which suggest that the costs will overtake the benefits with the omission of Fresh Cut and

unidentified illnesses. Other commenters recommend removing Fresh Cut produce from the estimation of illnesses due to RACs, and state that Fresh Cut produce most likely is contaminated outside of the farm and in the processing facility.

Response 38) FDA agrees that Fresh Cut should be omitted from the benefits analysis of the produce rule. We have, therefore, moved Fresh Cut from this FRIA related to the produce safety rule to the cost-benefit analysis related to PCHF rule. In terms of the unidentified illnesses, we have refined our estimation to be more conservative in terms of the number of unidentified illnesses. However, we have included an alternative calculation of benefits without unidentified illness in Table 11, which shows that omitting unidentified illnesses does not drastically change the benefits, and does not cause the costs to overtake the benefits.

Comment 39) One commenter states that many covered farms in North Carolina have made significant capital outlays in equipment appropriate to the scale of their operations, and will incur significant expenses in order to retrofit existing infrastructure. The commenter requests that FDA grandfather capital equipment for an additional seven years.

Response 39) We realize that replacing capital equipment, which typically has a long lifetime, would pose a significant burden to farmers; however, the rule has been written in a way that we expect to minimize such needs. The rule is not prescriptive as to the nature of tools or equipment used in covered activities by covered farms and, therefore, as long as relevant tools and equipment are of adequate design, construction, and workmanship to enable them to be adequately clean and properly maintained, it will not be necessary to replace a farm's tools or equipment to comply with this rule. To that

end we have estimated the cost of cleaning current capital equipment, rather than the replacement value. Additionally, to provide increased flexibility to all farms, we stagger compliance dates (see section XXIV of the rule).

Comment 40) One commenter states that the PRIA should reflect net profit instead of sales.

Response 40) We prefer sales rather than net profit because sales data serve as a proxy for total produce volume on a farm. Although we realize this is an imperfect measure, net profits could significantly understate the volume of food leaving any particular farm. Additionally, data on sales is easily observable and shared by many farmers, where information on profits is not.

II. Final Regulatory Impact Analysis

A. Background

Table 2 presents a side-by-side comparison of the estimated costs of the proposed rule and updated estimated costs of the final rule. To present a valid comparison, we have updated the (previously published) estimated costs of the proposed rule using the latest data and techniques. Estimated total steady state costs to domestic operations, using a 7 percent discount rate over 10 years, are \$530 million for the proposed rule, and \$560 million for the final rule.

Table 2. Comparison of Costs of the Rulemaking across Data Sources (in millions)

Cost Sections	Original Analysis With Updated Data	Final Analysis
Personnel Qualifications and training	\$124.12	\$187.38
Health and Hygiene	\$141.87	\$135.61
Agricultural water	\$58.94	\$37.07

Biological soil amendments of animal origin	\$9.19	\$2.47
Domesticated and wild animals	\$37.78	\$15.86
Growing, harvesting, packing, and holding activities	\$0.52	\$2.25
Equipment, tools, buildings, and sanitation	\$72.99	\$118.69
Sprouting operations	\$7.51	\$6.77
Recordkeeping	\$40.18	\$27.49
Administrative cost to learn the rule	\$34.31	\$23.25
Corrective steps	\$2.01	\$3.25
Variances	\$0.10	\$0.11
Total Costs (annual in millions)	\$529.51	\$560.19
Net present value (7 percent)	\$2,929	\$15,992
Annualized costs (7 percent)	\$417	\$366

Note: This table utilizes two different timing scenarios when calculating NPV. For the original analysis with updated data large farms are given an extra year for compliance, small farms are given two years, and very small farms are given three. The timing for the current analysis is more complex, and fully laid out in Table 4 of this analysis. Additionally the new timing allows farms more time to implement requirements, thus lessening the burden when discounted.

Using the steady-state comparison illustrated in Table 2, the final rule has estimated costs (\$560.16 million annually) that are 21.9 percent higher than the estimated costs of the proposed rule (\$459.56 million annually). This 21.9 percent increase in estimated costs is attributable to the changes in the provisions of the rule from the proposal to the final stage. Between the publication of the proposed rule and the final rule, however, we updated some of the data and techniques used to estimate costs. We have updated wage data, updated the way we account for overhead costs in relation to wages, updated data on the number of operations affected by the rule, and we adopted new techniques for modeling some of the provisions, based on comments and other information gathered since the publication of the proposed rule. The published estimate of the annualized costs of the proposed rule was \$459.56 million using a 7 percent discount rate (Ref. 6) The adjusted estimate of \$529.51 million in annual costs of the proposed rule in Table 2 above reflects a 15.2 percent increase compared to the previous

estimate, and this 15.2 percent increase is attributable to changes in the data and techniques used in our cost estimation, not changes in the provisions of the rule.

One significant cause for the increase in our estimated steady state cost is the change in our estimate of costs of labor hours. Following DHHS guidelines, we corrected our estimate for computing overhead costs to include a 100 percent adjustment relative to the money wage, rather than the 50 percent adjustment used in the original estimates. New DHHS guidelines, for computing labor costs recommend (based on general industry data) benefits plus other overhead costs equal 100 percent of pre-tax wages (Ref. 14). This correction results in a roughly 13.3 percent (\$66 million) increase in estimated costs. We also updated the base year for computing wage rates from 2010 to 2013, the most recent year for which the Bureau of Labor Statistics has complete wage rate data. This update alone results in a 2.9 percent (\$15.8 million) increase in costs. The sum effect of the two updates to the wage estimates results in a roughly 16 percent (\$81.8 million) change in estimated annualized costs.

We obtained more recent data for the farm count from the USDA, National Agriculture Statistical Service's (NASS) 2012 Census of Agriculture (Ref. 15) Our estimate of the total farms covered decreases from the 40,496 estimated in 2007 to 35,029 using the latest census numbers. The new farm count results in a 9 percent (roughly \$55.2 million) net decrease in costs.

Based on data and information gathered from and in response to public comments, as well as other new sources, we changed the way we modeled the cost estimates of a number of provisions. For example, we have increased the estimate for the number of operational days where the harvested or harvestable portion of produce is exposed,

increased the time estimated to inspect agricultural water sources and systems, decreased the time estimated for farms not covered or eligible for a qualified exemption to read and learn about the rule, and increased the average estimated cost of environmental testing for sprout operations and water testing for all covered farms. In addition, some of the proposed provisions in the 2013 proposed rule and the supplemental notice have changed for this final rulemaking. For example, the inclusion of an allowance for microbial die-off in relation to use of agricultural water during growing of covered produce (other than sprouts) using a direct water application method, has allowed us to reduce some of the burden to farmers. These adjustments led to changes in total estimated costs. The net effect of all of these changes from the proposed rule is a roughly 16.1 percent increase (almost \$73.4 million) in total estimated costs.

The combined effect of updating and correcting our method for estimating overhead costs, using the most recent baseline for calculating wage rates, the most recent farm count, and other adjustments to estimates based on public comment and changes to the regulatory requirements, change the steady state estimate of total domestic costs of the proposed rule from approximately \$459.56 million (the originally published estimate with no update to wages or data) to \$560.16 million, a 21.9 percent increase.

We use the revised wage rates, most recent base year, the revised farm count, and other adjustments throughout our analysis of the final rule.

The estimated benefits of the proposed rule and the updated estimated benefits of the final rule also differ. In all, the estimated number of prevented illnesses decreases by about two-thirds from the proposed rule to the final rule, while the total estimated benefits increase by about one-third. This somewhat counterintuitive change is due to an

increase in the dollar costs of illnesses, combined with new data and estimation methods for the number of illnesses.

The final rule uses a higher VSL and QALD than the proposed rule. The new VSL values are taken from Robinson and Hammitt (2015) (Ref. 16). They present a VSL of \$9 million and a QALD value of \$1,260, whereas the proposed rule uses a VSL of \$7.9 million and a QALD value of \$586. The updated values of both QALD and VSL lead to increases in the quantified burden of illnesses. The increase in QALD implies particularly large increases for illnesses that last for long periods of time, while the increase in VSL leads to greater increases when the percentage fatality rate associated with a particular illness is high.

An increase in data range, combined with a more conservative estimate of unidentified goods, leads to an increase in more burdensome illnesses, but a decrease in less burdensome illnesses (i.e., unidentified illnesses). The data used in the final rule covers 2003 through 2012, while the data in the proposed rule only covers 2003 through 2008. Because 2008 through 2012 saw the relative incidence of outbreaks associated with produce RACs rise, our estimated number of illnesses, which is based on the ratio of reported FDA-regulated produce RAC outbreaks to total CDC identified illnesses in the same time period, increased. This increase, however, was somewhat offset by the large decrease in unidentified illnesses. In the final rule, we employ the more conservative estimate, of the two published in the original analysis, of unidentified illnesses, which have a very low estimated cost per illness. This change strictly drives the number of unidentified illnesses down. We also omit outbreak illnesses associated with Fresh Cut

products, as they are now addressed in the Preventive Controls rule, which further reduces the estimated number of illnesses.

B. Need for Regulation

The need for this rule stems from a market failure caused by the asymmetric information associated with the safe production and consumption of raw agricultural commodities that are covered produce. If covered farms do not apply the socially optimal level of food safety practices, they create a potentially harmful situation for consumers, which is largely unobservable to consumers. There is not a sufficiently significant direct link between poor produce safety practices and food-related illnesses, which suggests that food safety is not an experience good (product for which characteristics, such as quality or price, are difficult to observe in advance, but can be ascertained upon consumption); with rare exceptions, the link between consumption of raw agricultural products and experiencing a food-related illness cannot be determined by consumers.

This final rule aims to reduce the effects of the information asymmetry by requiring certain science-based minimum standards for the safe growing, harvesting, packing, and holding of covered produce across all covered farms, thereby reducing foodborne illnesses from this source.

Using a science-based framework we characterize the magnitude of the public health risks associated with the consumption of produce, and establish specific standards that address the risks of microbial contamination from significant agricultural inputs (labor, water, biological soil amendments of animal origin, and tools and equipment), unsanitary conditions in buildings, and wild and domesticated animals, as well as the risks of microbial contamination in the production of sprouts. We provide a framework to

evaluate the effectiveness of the rule for addressing the public health risks associated with biological hazards in produce.

We define thresholds for different farm size categories that will be covered, with each farm size category linked to a quantitatively defined level of public exposure to risk.

We estimate the costs of each provision by farm size.

The rule also responds to lower-than-socially-optimal private incentives to provide safe practices. These are a result of uncertainties in the individual farm's understanding of the magnitude of the public health risk from the consumption of produce grown on their farm, as well as the effectiveness of measures and controls at addressing that risk. At this point in time, public health surveillance is often unable to determine whether an illness resulted from a foodborne pathogen or which particular food or food category may have served as the vehicle for the pathogen that caused the illness. It is also frequently unable to identify the specific farm or practice implicated in a produce-associated outbreak. This may result in the underestimation by producers of the costs to society from consuming produce and may cause them to discount the value of food safety practices and to provide less-than-the-socially optimal amount.

In addition, this rule responds to a statutory mandate in Section 419 of the Federal Food, Drug, and Cosmetic Act requiring that the Secretary of HHS adopt a regulation setting forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including those determined to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables, and to provide reasonable

assurances that the produce is not adulterated under Section 402 of the Federal Food, Drug, and Cosmetic Act.

C. Purpose of the Rule

The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The rule addresses microbiological risks from certain routes of contamination, including workers, agricultural water, biological soil amendments of animal origin, and tools and equipment, unsanitary conditions in buildings, and wild and domesticated animals during growing, harvesting, packing, and holding activities of covered produce, including sprouts.

D. Inputs and Assumptions

The following section outlines some of the standard information utilized throughout the remainder of the analysis. First, we present all standard cost estimates and assumptions that allow us to calculate the costs of implementation at the farm level. This section includes things like standard labor costs and data sets used to inform estimates and assumptions. Next, we provide information on the coverage of the analysis and how it relates to the US produce industry as a whole. Finally, we provide some information on the timing of both costs and benefits of this regulation. Detailed discussion of how these estimates and data are used to estimate industry costs are included in the detailed analysis of costs section.

Measuring Costs

We measure costs based on the best available information from government, industry, and academic sources. We list some common conventions used throughout the cost analysis here.

All wage rates used come from the Bureau of Labor Statistics (BLS),

Occupational Employment Statistics, May 2013, National Industry-Specific Occupational

Employment and Wage Estimates, under NAICS 11 – Agriculture, Forestry, Fishing, and

Hunting (Ref.17). Wages are increased by 100 percent to account for overhead.

- Farm Operator or Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for a farm operator or manager is \$72.12 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry as shown in (Ref.17) of \$36.06 and we add 100 percent for fringe benefits and other overhead costs (\$36.06) for a total estimate of \$72.12.
- Farm Supervisor Mean Wage Rate: Our estimate for the mean hourly wage rate for farm supervisors is \$42.74 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for First-Line Supervisors of Farming, Fishing, and Forestry Workers as shown in (Ref.17) of \$21.37 and we add 100 percent for fringe benefits and other overhead costs (\$21.37) for a total estimate of \$42.74
- Farm Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for farm workers (nonsupervisory) is \$18.56 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for Farmworkers and Laborers, Crop, Nursery, and Greenhouse as

shown in (Ref.17) of \$9.28 and we add 100 percent for fringe benefits and other overhead costs (\$9.28) for a total estimate of \$18.56.

We use the 2012 Census of Agriculture farm-level database to derive the total number of domestic farms (including greenhouses) that grow produce, the number of produce acres operated, the amount of labor employed, and their food sales; to estimate the number of farms that are eligible for the qualified exemption created by section 419(f) of the FD&C Act; and to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices). (Ref.18)

We use FDA's Operational and Administrative System for Import Support (OASIS) database to estimate the number of foreign farms that will be covered by the rule. (Ref.19)

We use the following surveys and literature where possible to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices):

- 1999 Fruit and Vegetable Agricultural Practices Survey (FVAP) (Ref.20)
- Farm Food Safety Practices: A Survey of New England Growers (Ref.21)
- Growers' Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs (Ref.22)
- USDA Agricultural Marketing Service (AMS) Fresh Produce Audit Verification
 Program, including commodity-specific audits for the tomato and mushroom industries (Ref.23).
- Food safety regulations and marketing agreements: Florida Tomato Regulation (Florida Rule 5G-6.011) (Ref.24), and the Leafy Greens Marketing Agreements in

California (Ref.25) and Arizona (Ref.26) (together, sometimes referred to as "LGMA").

National Agricultural Workers Survey (NAWS), U.S. Department of Labor,
 Public Access Database, 1989 to 2006, for years 2005 to 2006 to estimate the
 number of workers that are employed on multiple farms, and the number of
 workers employed by farm task; it is also used to create estimates of the rates of
 specific food safety practices currently being undertaken by farms (current
 industry practices) (Ref.27)

We annualize any one time costs over 10 years at discount rates of 7 percent and 3 percent. For ease of reading, in the main document, we report only results derived from the 7 percent discount rate. In the sensitivity analysis and summary sections, we also report results derived from the 3 percent discount rate

To classify farms that are covered by the rule by size, we identified farms as very small when they generate over \$25K but no more than \$250K annually in produce sales, small when they generate over \$250K but no more than \$500K annually in produce sales, and large when they generate more than \$500K annually in produce sales.

We estimate that very small farms operate 100 days out of the year where the edible portion of produce may be exposed, small farms operate 150 days, and large farms operate 200 days (non-consecutive).²

We estimate that the farm operator or manager is the person responsible for training on all farms.

² This estimate is based on annual planting data from USDA (Ref.18). This estimate is based on annual planting data from USDA (Ref.18).

For the purposes of this analysis, we use the term post-harvest activities to refer to all covered activities that occur after produce is removed from the growing area. We note that for the purposes of the rule, the term "harvesting" is broad enough to encompass some of these activities. We do not use the term "harvesting" in the same sense here but rather use it to refer only to removing produce from the growing area.

We use FDA's Evaluation of Recordkeeping Costs for Food Manufacturers, February 13, 2007, for our estimates for the hours necessary to perform the various recordkeeping functions, for our estimate of the frequency of recordkeeping by record type; and the average minutes spent keeping records by record type. Recordkeeping estimates in this report are based on expert opinion and an extensive literature review (Ref.7).

Coverage of the Analysis

1. All Farms

The rule applies to covered farms that grow covered produce including fruits and vegetables such as berries, leafy greens, herbs, and sprouts. It applies equally to farms located domestically and farms in foreign countries exporting covered produce to the US. There are approximately 121,116 farms in the U.S. that grow produce for sale excluding sprouting operations, which we analyze separately (Ref.18). This number was derived using the 2012 Census of Agriculture and includes farms with on-farm packing, greenhouses, farms eligible for qualified exemption (§ 112.5), farms that grow covered produce for commercial processing (§ 112.2(b)), and farms that are not covered by the rule (§ 112.4). We estimate that there are approximately 475 sprouting operations, which include farms eligible for qualified exemptions, and sprouting operations that are not

covered by the final rule. Sprouting operations will be considered in the sprouts section. We estimate that there are 70,395 foreign farms that will offer covered produce for import into the U.S., which includes farms eligible for qualified exemptions, and farms that are not covered by the final rule (Ref.19). This number was estimated using the number of foreign produce manufacturers in the OASIS database from fiscal year 2008, and multiplying it by the ratio of domestic farms to domestic manufacturers in the U.S.

2. Eligibility for Exemption and Corresponding Modified Requirements

The rule identifies certain farms and certain produce that are eligible for exemptions provided certain requirements are met. The eligibility for an exemption is established under two criteria: (1) the monetary value of all food sold on the farm and direct marketing of a portion of the food, and (2) produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g. a microbial kill-step). Farms, or produce, that qualify for either exemption are subject to a subset of the administrative provisions of the regulation, which are discussed in detail in the summary of records section of this analysis.

a. Monetary value of all food sold and direct farm marketing ("Qualified Exemption")

Farms are eligible for a qualified exemption if the average value of their food sales over the last 3 years was less than \$500,000 and if more than 50 percent of their food sales were direct sales to qualified end-users as that term is defined in the rule (see §§ 112.3(c), 112.5, 112.6, and 112.7). "Food" is defined in § 112.3(c) and Section 201(f) of the Federal Food, Drug, and Cosmetic Act. In order to estimate the number of farms that meet this qualification, we use data from the 2012 Census of Agriculture. We

estimate that there are approximately 3,134 total farms, including 171 sprouting operations, eligible for the qualified exemption after accounting for farms that are not covered, which is explained in part c. of this section, "Coverage of the Analysis".

b. Commercially processed produce

Produce that is commercially processed in a manner so as to adequately reduce pathogens is eligible for exemption from the rule provided that certain required steps are taken (see § 112.2(b)). Processing of low acid or acidified foods (in compliance with applicable FDA regulations in Parts 113 and 114) and processing of juice (in compliance with applicable FDA regulations in Part 120) are examples of eligible processing methods. Produce that is destined for the frozen or fresh-cut markets is typically not eligible since there is generally no adequate reduction of pathogens in the processing method.

We estimate the number of farms whose covered produce would qualify for this exemption using production information, specifically the amount sold to fresh versus processed markets, available in published reports for citrus, non-citrus, berries, vegetables, and tree nuts from the 2012 Census of Agriculture (Ref. 15). There are approximately 3,199 farms whose produce would qualify for this exemption, after accounting for farms that are not covered, and farms that do not also grow other covered produce. Farms that grow covered produce that is eligible for the commercial processing exemption and that also grow other covered produce will be subject to the regulation only with respect to their other covered produce.

3. Farms and produce not covered

Farms not covered by the regulation are those with an average annual monetary value of produce sold during the previous three-year period of \$25,000 or less (see § 112.4). Produce that is rarely consumed raw, such as beets, potatoes, sweet corn, and sweet potatoes, is also not covered by the rule (the rule includes an exhaustive list of such produce, from which we have provided only a few examples here) (see § 112.2(a)(1)). A farm that only grows these commodities, and does not also grow covered produce, will not be subject to the regulation. Farms that grow these commodities and covered produce will be subject to the regulation only with respect to their covered produce. Produce for personal or on-farm consumption is also not covered by the regulation (see § 112.2(a)(2)). A farm that only grows produce for personal or on-farm consumption, and does not also grow covered produce, will not be subject to the regulation. Farms that grow produce for personal or on-farm consumption and covered produce will be subject to the regulation only with respect to their covered produce.

The USDA National Commission on Small Farms defines a small farm as a family farm with less than \$250,000 total monetary value of food a year (Ref.28). The Commission's recommendation was based on the reasoning that these farms are the likeliest to exit the industry, and have the greatest need to improve net farm incomes since they receive only 41 percent of all gross sales revenue, but make up 94 percent of all U.S. farms (Ref.28). We use the \$250,000 monetary value of produce threshold for the upper end of our very small farm category. Covered produce farms below this threshold make up 17 percent of produce acres, and 87 percent of all produce farms. We use the monetary value cutoff of \$500,000 from the qualified exemption for direct farm marketing in § 419(f) of the FD&C Act as the upper end of our small farm category.

Farms below this \$500,000 threshold make up 24 percent of produce acres and 92 percent of all produce farms. Farms that are not covered because they have no more than \$25,000 in average annual monetary value of produce make up about 5 percent of produce acres, but 62 percent of all produce farms.

d. Summary of Farms Eligible for Exemption, Farms Not Covered, and Produce Not Covered

Table 3 shows the total number of domestic farms, the number of covered and exempt/not covered farms, and a breakdown of the number of farms that are eligible for a qualified exemption and that are not covered by the rule. All farm numbers are calculated from the NASS 2012 Census of Agriculture (Ref.18). Not accounting for sprouts, we estimate that there are a total of 21,666 farms that would be eligible for the qualified exemption, and 18,381 of those farms generate \$25,000 or less in produce sales and therefore are not covered. Similarly, we estimate that there are a total of 4,153 farms all of whose covered produce would be eligible for the commercially processed produce exemption, and 954 of these farms generate \$25,000 or less in produce sales and therefore are not covered. We estimate there are 16,190 farms not covered because they grow produce that is rarely consumed raw, and 11,518 of those farms generate \$25,000 or less in produce sales and therefore are not covered. Lastly, there are 44,078 farms not covered under this rule because they generate \$25,000 or less in produce sales and therefore are not covered. After accounting for those farms that are eligible for a qualified exemption and also generate \$25,000 or less in produce sales and therefore are not covered, we estimate that a total of 86,087 farms (21,666 + 4,153 + 16,190 + 44,078) are

not covered under the rule. The numbers for sprouting operations are covered in the sprouts section.

Table 3. Breakdown of Covered and Exempt Farms

	\$25K or less monetary value of produce produced	very small	small	large	Total
Total Produce Farms	74,931	30,952	5,128	10,105	121,116
Total Produce Acres	410,319	1,050,000	580,969	6,380,000	8,422,103
Qualified exemption farms	18,381	3,015	270	-	21,666
% total produce acres	1%	1%	1%	-	3%
Exempt produce – commercially processed	954	1,991	448	760	4,153
% total produce acres	1%	2%	1%	8%	12%
Not covered produce - rarely consumed raw	11,518	3,165	454	1053	16,190
% total produce acres	1%	2%	1%	9%	14%
Not covered farms -\$25,000 or less monetary value of produce	44,078	-	-	-	40,078
% total produce acres	2%	-	-	-	2%
Total Covered Farms	-	22,781	3,956	8,292	35,029
% total produce acres	-	7%	4%	58%	70%

The 21,666 'qualified exemption' farms, who have less than \$500K in average annual monetary value of food sales over a rolling 3-year period and sell over half of their food directly to qualified end-users, account for about 3 percent of all US produce acreage. The 74,931 farms that generate \$25,000 or less in produce sales, account for only 5 percent of all domestic produce acreage, but for 62 percent of all farms that grow produce. They have average produce sales of \$6,539 per farm and grow an average of 5.5 produce acres. After accounting for farms that would not be covered because they grow produce that is rarely consumed raw or that receives commercial processing, qualified exemption farms still account for about 2 percent of all covered domestic

produce acreage. After accounting for the farms that are eligible for a qualified exemption or that grow produce that is rarely consumed raw or commercially processed, then the leftover 44,078 not covered farms only account for about 2 percent of all domestic produce acreage. In total, the rule covers about 29 percent of all domestic produce farms, and about 94 percent of all domestic produce acres that are not dedicated to growing commodities rarely consumed raw or that will receive commercial processing. Timing of Costs and Benefits

Because the timing of the rule's compliance dates varies across provisions, by farm size, and for sprouts, it is necessary to discount these costs and benefits accordingly, as neither will be realized immediately. Table 4 presents the timing of all costs and benefits as they accrue across farm sizes for the first ten years after publication of this final rule. Zero costs and benefits are estimated to be incurred by covered farms in the first two years following publication, because all farms are given two years to implement the provisions of the rule (except with regard to sprouts, discussed separately below). In addition to this, all small farms are given an additional year and very small farms are given two additional years to implement the required provisions. Finally, all farms, regardless of size are given an additional two years from their specific compliance date to implement certain required water provisions (except with regard to sprouts).

In addition, the timing for sprout operations is different from other farms. Large sprouting operations have one year to comply with the rule, small sprouting operations have two years, and very small sprouting operations have three years, with no additional time for any particular provisions.

Finally, qualified exempt farms will have to begin complying with the record retention requirement for records supporting eligibility in § 112.7(b) upon the effective date of the rule, and with the modified requirement in § 112.6(b)(1) on January 1, 2020. Otherwise, qualified exempt small farms will have three years to comply with the remaining modified requirements in §§ 112.6 and 112.7, and very small qualified exempt farms will have four years. We do not explicitly estimate a cost to keeping the records required by 112.7(b), as we expect that such records would be kept under normal business practices.

Table 4. Timing of Produce Costs and Benefits

Tubic 4.		ming of i	Touret C	osis and b	CATCHES					
Farms	Yearl	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered	Farn	ns								
Very Small			ŧ.	i	Costs/ Benefits Less Water ¹ (CBLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB
Small	1	-		Costs/ Benefits Less Water ¹ (CBLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB
Large	1	1	Costs/ Benefits Less Water(C BLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB
Covered	Spro	ut Operati	ons							
Very Small Sprouts			- 	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB
Small Sprouts			Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB	FCB
Large Sprouts		Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB	FCB	FCB

Exempt F	arm	ıs								
Very Small Exempt				1	Full Costs (FC)	FC	FC	FC	FC	FC
Small Exempt				Full Costs (FC)	FC	FC	FC,	FC	FC	FC
Large Exempt			Full Costs (FC)	FC	FC	FC	FC.	FC	FC	FC

Note: Certain water testing-related provisions are delayed by two years from initial compliance dates.

Throughout the remainder of this document, we estimate the annual costs of compliance across farm sizes and provisions, as well as the benefits that are likely to occur; these are the primary estimates presented in the benefits or specific costs calculations. Following this, to reflect the nature of the way these costs and benefits will be realized, we take a net present value (NPV) over these 10 years for both costs and benefits, and we annualize them according to the table above, using both a 3 and 7 percent discount rate. Both costs and benefits are discounted in the same manner to provide easily comparable annualized estimates.

E. Benefits of the Rule

The primary benefits of the provisions in this rule are an expected decrease in the incidence of illnesses relating to produce from microbial contamination. For the purpose of this analysis, we develop a conceptual framework that describes how implementing this rule is likely to reduce the level of foodborne illness.

1. Baseline Risk of Foodborne Illness³

³ The estimated burden of illness and subsequent estimations of rule benefits include illnesses occurring in the U.S. tied to imported produce. We do not attempt to estimate the benefits that would accrue due to the mitigation of produce related illness in other countries due to improvements in the safety of U.S. exports or produce grown and consumed in other countries on farms covered by the rule. A rough estimate of costs

To estimate the number of baseline illnesses attributable to produce from microbial contamination only, we begin with only those outbreaks we can directly attribute to FDA-regulated produce that has suffered microbial contamination. Table 5 presents all outbreaks, organized by produce commodity and pathogen, which can be linked to microbial contamination of produce raw agricultural commodities (RAC) other than sprouts, and sprouts (treated separately), based on illnesses recorded in FDA's outbreak database (Ref. 29). This does not include Fresh Cut (FC), which are not RACs. In total, there are 69 outbreaks, 7,050 illnesses, and 46 deaths in the FDA database attributable to FDA-related produce. This averages out to about 7 outbreaks, 705 illnesses, and 4.6 deaths per year observed in the outbreak database.

The data span of 2003-2012 is utilized for this analysis because it represents the most current, and comprehensive data available. We are unable to look at years beyond 2012, because the full outbreak data, from CDC, has not been completely collected, sorted, cleaned, and made available for public use. Additionally, collection methods by both FDA and CDC have improved vastly in recent years, and data further back may be more subject to underreporting biases. It is important to note that our data span differs from that of the PRIA (Ref. 6), which uses the years, 2003-2008. This drives up the raw numbers of outbreaks, cases, hospitalizations, and deaths in this final RIA, but does not necessarily impact our annual estimates. The fact that the years 2008 through 2012 saw a higher relative incidence of FDA covered RAC attributable illnesses than the previous years does drive up the ratio of reported FDA RAC outbreaks to total CDC identified

illnesses. The implications of extending the outbreak data to 2012 are further discussed in the Uncertainty and Sensitivity Analysis section.

Table 5. FDA Outbreak Data, 2003-2012

Outbreak Data A	attributed to Produce RACs (Other Than Spr	outs 2003	-2012	
Commodity	Agent	Outbreaks	Cases	Hospitalizations	Deaths
berries	Cyclospora	2	67	, 2	0
berries	Salmonella	2	20	1	0
green onion	Hepatitis A	1	919	128	3
herb	Cyclospora	2	622	1	0
herb	E. coliO157:H7	1	108	8	0
leafy greens	Cyclospora	1	38	0	0
leafy greens	E. coliO157:H7	3	60	15	0
leafy greens	Salmonella	1	15	1	0
melon	Listeria monocytogenes	1	147	143	33
melon	Salmonella	8	514	140	6
melon	Shigella sonnei	1	56	3	0
nut*	E. coliO157:H7	1*	8*	3*	0*
nut	Salmonella	2	95	12	1
other	Cyclospora	2	172	. 0	0
other	Salmonella	6	1925	370	2
tomato	Salmonella	8	661	80	0
unknown	Salmonella	- 6	860	132	0
RAC Total		48	6287	1039	45
Outbreak Data A	attributed to Sprouts, 2003-20)12			
sprout	E. coliO157: NM (H-)	3	36	3	0
sprout	E. coliO157:H7	2	27	5	0
sprout	E. coliO26	1	29	7	0
sprout	Listeria monocytogenes	1	20	16	0
sprout	Salmonella	14	651	56	1
Sprout Total		21	763	87	1
Total		69	7050	1126	46

Note: The E. Coli nut outbreak is associated with hazelnuts, which are not covered by the final rule (they are exempt as rarely consumed raw under § 112.2(a)(1)). Therefore we do not include this outbreak in calculating the estimated benefit of the rule.

Table 6 presents the estimation of the total number of illnesses attributable to produce RACs other than sprouts based on FDA outbreak data combined with CDC outbreak data (Ref. 30) and applied to Scallan, et al.'s estimate of the total number of foodborne illnesses (Ref.31). To estimate the number of total illnesses associated with

FDA regulated produce, we employ a two-step calculation, fully explained in the Preliminary Regulatory Impact Analysis (Ref. 6): First, to determine the percent of illness attributable to produce we examine FDA specific outbreak data and the whole universe of identified pathogen illnesses, accounting for all outbreaks associated with an identified food vehicle. Dividing the number of observed FDA-regulated produce-associated illnesses by the total outbreak illnesses, gives us the percentage attributable to FDA-regulated produce. This number is then multiplied by Scallan, et al.'s estimate of the total annual incidence of each specific foodborne pathogen (Ref.31). This step corrects for numerous downward biases in the CDC database of illnesses such as under-reporting and under-identification of a foodborne illness. Multiplying the percentage attributable to FDA-regulated produce by the annual incidence yields the annual estimated illnesses attributable to FDA-regulated produce.

Dividing the number of produce acres associated with covered farms by the number of produce acres more susceptible to contamination resulting in preventable illness (i.e., produce that is not commercially processed or rarely consumed raw), we find that approximately 94.2 percent of produce acres associated with preventable illness are covered by the produce rule. This means that 5.8 percent of produce associated with illnesses potentially preventable by the rule is exempt or not covered. If the marginal risk of illnesses associated with a unit of output were distributed uniformly across farms within a given commodity, 4 then we could see a total reduction in preventable illnesses of

⁴ There has been no evidence to suggest that the marginal risk of illness from a unit of output on large farm is smaller or larger than the marginal risk of illness from a unit of output on a small farm.

about 5.8 percent, or to 130,398 (138,424 x [1-.058]) for produce RACs other than sprouts and 52,888 (56,145 x [1-.058]) for sprouts.⁵

We multiply the total number of estimated preventable illnesses attributable to FDA regulated produce (130,398+52,888 = 183,826) by 4 to obtain 733,146 unidentified illnesses. This creates a ratio of identified to unidentified illnesses that is consistent with Scallan, et al., who estimate that unidentified illnesses make up about 80% of all foodborne illnesses (Ref.31). Using this calculation methodology, the total number of preventable foodborne illnesses caused by microbial contamination of FDA-regulated produce is estimated to be 916,432 (183,826+733,146, rounded). This is the more conservative of the two estimation methods presented in the PRIA (Ref. 6), which reduces our estimate of total unidentified illnesses.

Table 6. Estimated Number of Illnesses

Estimated Number of III	nesses Attribut	able to Produ	ce RACs other t	han sprouts	
Agent	FDA RAC (2003-2012)			Estimated Annual Foodborne Illnesses (Scallan)	Estimated Annual Illnesses Attributable to RACs
Salmonella	4,090	36,790	11.12%	1,072,450	119,226
Shigella sonnei	56	3,044	1.84%	154,053	2,834
Listeria monocytogenes	147	361	40.72%	1,680	684
Hepatitis A	. 919	1,250	73.52%	1,665	1,224
Cyclospora cayatenensis	899	1,109	81.06%	13,906	11,273
E.coli, STEC0157	168	3694	4.55%	69,972	3,182
Total Identified RAC	6,279	46,349	13.56%	1,438,692	138,424
Estimated Number of Ill	nesses Attribut	able to sprou	ts		
Agent	FDA Sprouts (2003- 2012)	Identified Cases (2003- 2012)	Percentage Attributable to Sprouts	Estimated Annual Foodborne Illnesses (Scallan)	Estimated Annual Illnesses Attributable to Sprouts

⁵ We do not consider there to be a significant drop in benefits due to the exclusion of produce rarely consumed raw or produce headed for commercial kill step processing, as such produce can be expected to receive treatment to reduce risk from biological hazards and is therefore considered to present lower risk than other types of produce.

Salmonella	651	36,790	1.77%	1,072,450	18,977
Listeria monocytogenes	20	361	5.54%	1,680	93
E.coli, STEC0157	63	3,694	1.71%	69,972	1,193
E.coli, STEC non 0157	29	101	28.71%	124,966	35,881
Total Identified sprouts	763	46,349	1.65%	1,438,692	56,145

We estimate the monetized value of reducing foodborne illnesses from produce by multiplying the annual number of illnesses per pathogen by the estimated cost (including willingness-to-pay for longevity and avoided pain and suffering) per case. The estimated cost per case is a pathogen specific estimate of dollar burden a typical case of this particular foodborne illness places on an individual, which comes from Minor et al (2014) (Ref. 32). Our estimated costs per illness are higher than those in the PRIA because we utilize a higher Value of Statistical Life (VSL), \$9 million, and a higher QALD estimate, \$1,260, for all pathogens (Ref. 16). Table 7 presents the burden of illness attributable to microbial contamination of FDA-regulated produce RACs other than sprouts and sprouts. Column two contains the total number of preventable illnesses attributable to FDA-regulated produce, previously calculated. This number is multiplied by the expected dollar loss per case, to give the annual cost of each pathogen in the US population. Taken together, we estimate that the total cost of the illnesses linked to all items of produce is approximately \$2.5 billion. As discussed below, these figures are not the expected benefits associated with the provisions in this rule. We expect that the rule would eliminate only some portion of illnesses linked to produce and so would have lower real-world benefits.

Table 7. Estimated Dollar Burden of Illnesses

Estimated Dollar Burden Attributable to Produce RACs other than sprouts

Agent	Est. Annual Illnesses Attributable to RACs	% produce acres associated with preventable illness	Est. Preventable Attributable Illnesses	Expected Dollar Loss per Case	Covered Dollar Burden (millions)
Salmonella	119,226	94.2%	112,311	\$6,015	\$676
Shigella sonnei	2,834	94.2%	2,670	\$3,323	\$9
Listeria monocytogenes	684	94.2%	645	\$1,574,670	\$1,015
Hepatitis A	1,224	94.2%%	1,154	\$46,704	\$54
Cyclospora cayatenensis	11,273	94.2%	10,620	\$4,056	\$43
E.coli, STEC0157	3,182	94,2%	2,998	\$11,631	\$35
Total RAC Identified	138,575	94.2%	130,398		\$1,831
Total RAC Unidentified	-		521,592	\$409	\$214
Total RAC	-		651,990		\$2,045
Estimated Dollar Burden	Est. Annual Illnesses Attributable to RACs	% produce acres associated with preventable illness	Est. Preventable Attributable Illnesses	Expected Dollar Loss per Case	Covered Dollar Burden (millions)
Salmonella	18,977	94.2%	18,977	\$6,015	\$108
Listeria monocytogenes	93	94.2%	93	\$1,574,670	\$138
E.coli, STEC0157	1,193	94.2%	1,193	\$11.631	\$13
E.coli, STEC non 0157	35,881	94.2%	35,881	\$2,253	\$76
Total Sprouts Identified	56,145	94.2%	52,888		\$335
Total Sprouts Unidentified	-		211,554	\$409	\$87
Total Sprouts Officentified					
Total Sprouts	-		264,442		\$421

2. Produce Rule Model of Risk Reduction

We examine the overall effectiveness of the regulation in reducing human foodborne illnesses. To do this, we estimate the public health benefits of the produce regulation provisions in two distinct ways: as a whole and by pathways of contamination. We specify eight pathways of contamination: Agricultural Water for growing and harvest activities; Agricultural Water for postharvest activities; Biological Soil Amendments;

Worker Health and Hygiene in growing and harvest activities; Worker Health and Hygiene in postharvest activities; Domesticated and Wild Animals; Equipment, Tools, Buildings, and Sanitation in growing and harvest activities; and Equipment, Tools, Buildings, and Sanitation in postharvest activities. These pathways come from the Qualitative Assessment of Risk (QAR), which defines five routes of contamination: Water, Soil Amendments, Animals, Worker Health and Hygiene, and Equipment and Buildings (Ref. 33). We split Water, Worker Health and Hygiene, and Equipment and Buildings into two separate pathways each, based on timing (growing and harvest versus postharvest activities), for a total of eight pathways. These eight pathways are addressed by an Expert Elicitation, the results of which are used to assign risk reduction values to each pathway (Ref. 34).

We estimate the change in the probability of produce contamination as a function of the relative likelihood of contamination from each specific pathway and the effectiveness of the rule in reducing the risk of produce contamination within a specific pathway of contamination. This change in the probability of contamination is then applied to the current baseline of preventable foodborne illnesses attributable to FDA-regulated produce. Based on current scientific literature, expert elicitation, census data, research, and outbreak investigations, we can estimate the range of measureable effectiveness of the produce safety regulation on the current burden of illness as a whole (Ref.34;35;36;37). Additionally, these data are stratified to examine the effect amongst specific commodities, or contamination pathways.

Table 8 presents the associated illnesses and mean relative weights and effectiveness used in the model, as well as the calculation of the percentage reduction in

contamination, by pathway and for the rule as a whole. For more detailed information on how the weights and effectiveness values are assigned, see the PRIA and relevant sources (Ref. 6;34;36;37). Because the weights and the effectiveness values are based on the average values of distributions, we acknowledge the uncertainty they introduce. We account for this in our uncertainty analysis of benefits in Section II, subsection I, (formerly addressed in section IV, subsection H, subsection 3 in the PRIA). In the uncertainty analysis, we run Monte Carlo simulations in which the values of the weights and effectiveness, among others, vary based on our calculated parameters of their distributions (mean, 5th percentile, 95th percentile). This allows us to calculate low and high estimates of the benefits, taking into account the possible uncertainty of the weights and effectiveness values.

To translate this percentage reduction in farm contamination to human health outcomes, we estimate that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses. This means that roughly a 56 percent reduction in contamination will similarly reduce costs of illnesses. We apply this percentage reduction to the average cost of illness, specific to produce-associated illnesses, to estimate the overall benefits of the rule through illness prevention. We can also use these assumptions to examine potential benefits of this rule by contamination pathway. These calculations are also presented in Table 8.

Table 8. Mean Reduction in Risk of Contamination/ Benefits by Pathway

Mean Reduction in Risk	Mean Reduction in Risk of Contamination/ Benefits by Pathway attributable to Produce RACs other										
than sprouts											
Contamination	Covered Dollar	Likelihood of	Effectiveness	Reductio	Benefits						
Pathway	Burden	Being the Path	of Controls	n in Risk	(millions)						
1	(millions)	of		,	`						
		Contamination	· .								
Agricultural Water (growing/harvest)	\$2,045	16.32%	54.49%	8.89%	\$182						

Agricultural Water	\$2,045	14.37%	72.55%	10.42%	\$213
(postharvest)					
Biological Soil	\$2,045	13.81%	65.62%	0.7%*	\$15
Amendments					
Worker Health and	\$2,045	15.62%	66.04%	10.32%	\$211
Hygiene	•				
(growing/harvest)					
Worker Health and	\$2,045	15.20%	73.50%	11.17%	\$228
Hygiene (postharvest)					
Domesticated and Wild	\$2,045	14.09%	58.04%	8.18%	\$167
Animals					
Equipment, Tools,	\$2,045	4.18%	56.71%	2.37%	\$49
Building and Sanitation	, ,				
(growing/harvest)			'		
Equipment, Tools,	\$2,045	6.42%	67.97%	4.36%	\$89
Buildings and					
Sanitation (postharvest)					
Total				56.43%	\$1,154
Mean Reduction in Risk	of Contamination	Benefits by Pathy	vav attributable	to sprouts	
Contamination	Covered Dollar	Likelihood of	Effectiveness	Reductio	Benefits
Contamination	Cottled Donas				
Pathway**	Burden				(millions)
Pathway**	Burden (millions)	Contamination	of Controls	n in Risk	(millions)
	(millions)	Contamination	of Controls	n in Risk	
Agricultural Water					(millions)
Agricultural Water (growing/harvest)	(millions) \$421	Contamination	of Controls 54.49%	n in Risk 8.89%	\$38
Agricultural Water (growing/harvest) Agricultural Water	(millions)	Contamination	of Controls	n in Risk	
Agricultural Water (growing/harvest) Agricultural Water (postharvest)	(millions) \$421 \$421	16.32% 14.37%	of Controls 54.49% 72.55%	n in Risk 8.89%	\$38
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil	(millions) \$421	Contamination	of Controls 54.49%	n in Risk 8.89%	\$38
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments	(millions) \$421 \$421 \$421	16.32% 14.37% 13.81%	of Controls 54.49% 72.55% 65.62%	8.89%	\$38 \$44
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and	(millions) \$421 \$421	16.32% 14.37%	of Controls 54.49% 72.55%	n in Risk 8.89%	\$38
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene	(millions) \$421 \$421 \$421	16.32% 14.37% 13.81%	of Controls 54.49% 72.55% 65.62%	8.89%	\$38 \$44
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest)	\$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62%	of Controls 54.49% 72.55% 65.62% 66.04%	n in Risk 8.89% 10.42%	\$38 \$44 - \$44
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and	(millions) \$421 \$421 \$421	16.32% 14.37% 13.81%	of Controls 54.49% 72.55% 65.62%	8.89%	\$38 \$44
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest)	\$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62%	of Controls 54.49% 72.55% 65.62% 66.04%	n in Risk 8.89% 10.42% 10.32%	\$38 \$44 - \$44 \$47
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild	\$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62%	of Controls 54.49% 72.55% 65.62% 66.04%	n in Risk 8.89% 10.42%	\$38 \$44 - \$44
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals	\$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 14.09%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18%	\$38 \$44 \$44 \$47 \$35
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools,	\$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62%	of Controls 54.49% 72.55% 65.62% 66.04%	n in Risk 8.89% 10.42% 10.32%	\$38 \$44 - \$44 \$47
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools, Building and Sanitation	\$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 14.09%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18%	\$38 \$44 \$44 \$47 \$35
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools, Building and Sanitation (growing/harvest)	\$421 \$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 15.20% 14.09% 4.18%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04% 56.71%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18% 2.37%	\$38 \$44 - \$44 \$47 \$35 \$10
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools, Building and Sanitation (growing/harvest) Equipment, Tools,	\$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 14.09%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18%	\$38 \$44 \$44 \$47 \$35
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools, Building and Sanitation (growing/harvest) Equipment, Tools, Buildings and	\$421 \$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 15.20% 14.09% 4.18%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04% 56.71%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18% 2.37%	\$38 \$44 - \$44 \$47 \$35 \$10
Agricultural Water (growing/harvest) Agricultural Water (postharvest) Biological Soil Amendments Worker Health and Hygiene (growing/harvest) Worker Health and Hygiene (postharvest) Domesticated and Wild Animals Equipment, Tools, Building and Sanitation (growing/harvest) Equipment, Tools,	\$421 \$421 \$421 \$421 \$421 \$421 \$421	16.32% 14.37% 13.81% 15.62% 15.20% 14.09% 4.18%	of Controls 54.49% 72.55% 65.62% 66.04% 73.50% 58.04% 56.71%	n in Risk 8.89% 10.42% 10.32% 11.17% 8.18% 2.37%	\$38 \$44 - \$44 \$47 \$35 \$10

^{*}The estimated effectiveness of Biological Soil Amendments has changed from the PRIA, because certain proposed requirements for this section have been removed in the rule (see § 112.56(a)(1)(i)). See below for a full explanation of the calculations. ** We do not have data to estimate risk reduction due to sprout specific contamination pathways and therefore analyze the same pathways for sprouts as we do for other produce.

From the table, we see that Agricultural Water for growing and harvest activities is estimated to be the most important pathway of contamination, at about 16 percent. This

is followed by Worker Health and Hygiene in postharvest activities (16 percent), Worker Health and Hygiene in growing and harvest activities (15 percent), and Domestic and Wild Animals (14 percent). Equipment, Tools, Buildings, and Sanitation in growing and harvest activities represents the lowest contamination pathway, accounting for only about 4 percent overall.⁶

We also see that the rule is estimated to do the best job of controlling risk of contamination for Worker Health and Hygiene in postharvest (ph) activities, about a 74 percent reduction. This is followed closely by controls on Agricultural Water used in postharvest activities (ph), estimated to have around 73 percent effectiveness in reducing the associated risks of contamination. Controlling Agricultural Water used for growing and harvest (g/h) activities is estimated to have the lowest effectiveness, at about 55 percent.

Provisions covering worker health and hygiene in postharvest (g/h) activities are estimated to have the most impact on overall contamination, reducing it by an estimated 11 percent. Provisions covering Equipment, Tools, Buildings, and Sanitation in growing and harvest (g/h) activities are estimated to contribute the least, at only about a 2 percent reduction in contamination.

Taken together, this adds up to about a 56.43 percent reduction in risk of contamination for produce RACs other than sprouts, and 55.71 percent reduction risk of

⁶ The number of outbreaks attributed to Equipment, Tools, Buildings, and Sanitation may be biased for a few reasons. When it is implicated in the data, outbreaks are typically associated with multiple contamination pathways, forcing the illnesses to be split amongst them, lowering the overall share of illnesses attributable to this specific pathway. Additionally, problems with things like sanitation or tools may be incorrectly attributed to another category, like worker health and hygiene. It could be that a worker improperly washes their hands or cleans their tools because sufficient hand-washing facilities or cleaning materials were not provided; however, when a resulting outbreak is recorded, only worker contact may be cited as a contamination pathway. With the current data available, these are only speculations, and we assign illnesses based only on the observable data.

contamination for sprouts. Note, in Table 8, we only account for a very small reduction in risk associated with our requirements related to Biological Soil Amendments because certain proposed requirements that we accounted for in the PRIA have now been eliminated from the rule (see § 112.56(a)(1)(i)). The originally estimated benefits attributable to Biological Soil Amendments would have contributed an approximate \$226 million in additional benefits (or 9.06 % of all foodborne illnesses attributable to FDA RACs). We estimate that the remaining provisions will produce smaller costs and benefits than previously estimated. Since the use of most Biological Soil Amendments of Animal Origin in growing covered root crops is prohibited by the rule (because it is not possible to minimize the potential for contact between soil amendments and root crops, only amendments that meet the requirements of 112. 55(a) may be used in growing covered root crops), we turn our focus to root crop farms. The proportion of covered non-sprout farms that grow root vegetables is 8% (Ref. 15). Therefore, we estimate that the benefits associated with the remaining requirements of BSA are 0.7% (9.06% x 8%) of all foodborne illnesses attributable to FDA regulated produce RACs other than sprouts, or approximately \$15 million.

We are unable to account for the provisions specific to sprouts, namely batch testing, seed treatment, and environmental monitoring because we are unable to parse out their individual effects beyond what has already been done for all covered produce. However, Ding and Fu (2013) (Ref. 38) and Montville and Schaffner (2004) (Ref. 39), suggest that these sprout-specific provisions are effective in reducing or preventing contamination. Therefore, our estimates likely represent a low estimate of the reduction in risk of foodborne illnesses attributable to sprouts.

Table 9 shows the estimated reduction in illnesses that may be attributable to the regulation, shown both in illnesses averted and total dollar costs attributable to those avoided illnesses. The overall benefits are higher than those in the PRIA, yet the number of illnesses prevented is lower than that of the PRIA. This is mainly attributable to the higher annual incidence of identified outbreaks associated with produce RACs other than sprouts and sprouts. Combined with a more conservative estimate of unidentified goods, which have a very low estimated cost per illness, we estimate a lower number of total illnesses, which have a higher average costs per illness.

Table 9. Summary of Annual Benefits of Produce Regulation

	Reduction in Risk	Illnesses Attributable to Produce Covered by this Rule	Illnesses Prevented	Cost Per Illness	Total Benefits (in millions)
Produce RACs other than sprouts	56.43%	651,990	367,949	\$3,136	\$1,1154
Sprouts	55.71%	264,442	147,321	\$1,593	\$235
Total		916,432	515,269		\$1,389

We estimate that this rule may prevent, when fully implemented, about 515,269 illnesses, with an associated benefit of approximately \$1.4 billion, annually. Furthermore, the effectiveness of the rule may increase over time as farms learn by doing. However, these benefits of this rule will not be immediately realized, nor will they be uniformly implemented, due to the staggered nature of compliance times. Table 10 presents the annual values of benefits as they are estimated to occur.

Table 10. Timing of Produce Benefits (in millions)

I WOLV I	•	11111119 01	I I Ou u CC I	301101103 (1						
Farms	Year1	Year 2	Year, 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered 1	Farn	ns								

Very Small	0	0	0	0	\$90	\$90	\$137	\$137	\$137	\$137	
Small	0	0	0	\$50	\$50	\$76	\$76	\$76	·\$76	\$76	
Large	0	0	\$620	\$620	\$942	\$942	\$942	\$942	\$942	\$942	
Covered Sprout Operations											
Very Small Sprouts	0	0	0	\$28	\$28	\$28	\$28	\$28	\$28	\$28	
Small Sprouts	0	.0	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$15	
Large Sprouts	0	\$191	\$191	\$191	\$191	\$191	\$191	\$191	\$191	\$191	
Exempt a	nd N	Not Covere	d Farms								
Very Small Exempt	0	0	0	0	0	0	0 ·	0	0	0	
Small Exempt	0	0	0	0	0	0	0	' 0	0	0	
Large Exempt	0	0	0	0	0	0	0	0	0	0	

The annualized benefits in Table 10 are calculated based on timing of produce costs and benefits schedule shown in Table 4. For example, in year 2, full benefits are realized from large sprout operations (roughly \$191 million, which is calculated as the total benefits attributable to sprouts operations multiplied by the percentage of covered farms that fall into the large category). Because no other farms are affected, no other benefits are being realized in year 2. This means that the total benefits realized in year 2 are roughly \$191 million. In year 3, full benefits are realized from large sprout operations (\$191 million). Also in year 3, full benefits are realized from small sprout operations (\$15 million, which is calculated as the total benefits attributable to sprouts operations multiplied by the percentage of covered farms that fall into the small category), and benefits minus those related to certain water provisions, are realized from large covered, non-sprout operations (roughly \$620 million, which is calculated as the total benefits attributable to certain

water provisions, multiplied by the percentage of covered farms that fall into the large category). This means that the total benefits in year 3 are roughly \$826 million. This continues, and in year 7, all benefits are realized, continuing on through our examined timeline. Adding over the different operation types and sizes for year 7 yields our full benefit estimation of roughly \$1.4 billion. This is also the case for year 8, year 9, and onward.

Next, we annualize estimates of the benefits below in Table 11. In this estimate, we take into account the time that different sized farms have to comply with the rule, as well as the different compliance times (notably, for agricultural water provisions, the initial survey testing requirement for untreated surface water used for direct water application during growing for produce other than sprouts, and certain related provisions, are subject to the earlier compliance dates). Estimates are annualized over 10 years.

Table 11. Net Present Value and Annualized Benefits of Produce Regulation

	Annualized Quantified Illnesses	Annualized Monetized Benefits (millions)
Net present value at 3 percent	3,181,093	\$8,322
Net present value at 7 percent	2,494,785	\$6,498
Annualized Values		
Annualized @ 3 percent over 10 years	362,059	\$976
Annualized @ 7 percent over 10 years	331,964	\$925
Excluding Unidentified Illnesses		
Annualized @ 3 percent over 10 years	72,411	\$854
Annualized @ 7 percent over 10 years	66,392	\$809

Annualizing benefits over the first ten years after publication of the rule, benefits are expected to be approximately 362,059 illnesses averted per year, valued at \$976 million annually.

F. Costs of the Rule

With the data available we have attempted to accurately estimate the baseline safety practices of the produce industry, and the costs related to the changes in those practices as required by the rule. We utilize the most current and representative data available.

We estimated most of the costs of the rule in the PRIA (which accompanied the 2013 proposed rule) and supplemental analysis (which accompanied the supplemental notice), which contain detailed explanations of all calculations (Ref. 6) Where costs have not changed substantially from those presented in either the proposed or supplemental analysis, we do not present those detailed estimates here. Instead, we provide the summary tables of the relevant Subpart, noting that only wages and farm counts have changed, while underlying methodology and requirements remain constant.

1. Personnel and Training (Subpart C)

We did not receive substantial comments on the cost estimates for Personnel and Training requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart C do not affect our cost estimates. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 12 provides the total cost for Personnel and Training; for full information on how these costs are estimated please refer to Tables 112-115 of the original PRIA (Ref. 6). The underlying estimates of this section have not changed; however, these requirements are almost exclusively reliant on labor hours so the increase

in wage rates has increased the costs. Also, based on public comments we increased the wage rate of the training official from a supervisor to operator level, which accounts for the majority of the increase in costs from those presented in the PRIA.

Table 12. Total costs for personnel qualifications and training (in thousands)

	Very Small	Small	Large	Total
Outside Training	\$2,975	\$517	\$714	\$4,205
Management Personnel Food Safety	\$880	\$465	\$940	\$1,986
Personnel Food Safety Training	\$4,118	\$2,637	\$7,576	\$14,330
Ensuring Personnel Compliance with	\$33,171	\$50,760	\$82,932	\$166,863
Total Costs Accrued to Farms	\$41,143	\$54,078	\$92,162	\$187,383

2. Health and Hygiene (Subpart D)

We did not receive substantial comments on the cost estimates for Health and Hygiene requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart D do not affect our cost estimates. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 13 provides the total cost for Personnel and Training; for full information on how these costs are estimated please refer to Tables 35 – 39 of the original PRIA (Ref. 6)

Table 13. Total Cost for Health and Hygiene (in thousands)

	Very Small	Small	Large	Total
Costs to exclude ill workers	\$1,808	\$723	\$5,845	\$8,377
Costs to wash and dry hands thoroughly	\$12,653	\$10,176	\$82,090	\$104,919
Costs to avoid contact with animals	\$121	\$98	\$676	\$896

⁷ There is new language that requires jewelry to be removed or covered and prohibits eating, chewing gum, or consuming tobacco in certain areas. We estimate that farms are largely already in compliance with this language and therefore do not present new estimates.

Costs to wash hands before glove use and maintain/replace gloves	\$380	\$306	\$2,467	\$3,153
Costs to inform, ensure compliance by, and have toilets for visitors	\$13,144	\$2,282	\$2,835	\$18,261
Total Costs (annual)	\$28,107	\$13,585	\$93,914	\$135,606

3. Agricultural Water (Subpart E)

Agricultural water has undergone the most changes due to changes in requirements from those proposed, public comments, and updated data. Therefore, we lay out all estimates related to Agricultural water below. The most significant impacts on the estimated costs from those presented in the proposed analysis are: increased our assumption about the time it takes for farms to conduct a water system inspection based on public comments; reduced the number of annual tests a farm must conduct due to changes in the rule's requirements; increased the number of farms that are required to conduct water testing, as this requirement does not apply to only farms with post-harvest activities; and allowed for die-off as a means to avoid water treatment, due to changes in the rule's requirements. Although some of these changes served to increase the costs of the Agricultural Water requirements, such as broader application of water testing and increased time to inspect water systems, the overall impact of these changes serves to reduce the costs of the Agricultural Water requirements, where changes in the rule's requirements have led to the largest reductions in costs.

We estimate the cost of inspecting water systems, in accordance with § 112.42, for the proportion of covered farms that are not currently conducting inspections; we find that 22,781 very small, 3,956 small, and 8,292 large farms will need to implement inspections. We estimate that very small and small farms will take four hours annually to inspect agricultural water systems and that large farms will take eight hours annually, this

estimate is based on data cited in the PRIA (Ref. 6) and public comments received on the same document. We multiply these time burdens by the average farm operator wage rate and estimate an annual per farm inspection cost of \$288 for very small and small farms, and \$342 for large farms. Table 14 presents the total cost of inspecting water systems.

These estimates are largely taken from the PRIA (Ref. 6) with the exception of hours to inspect which has been increased in response to comments.

Table 14. Cost of inspecting water systems

	Very Small	Small	Large	Total
Number of covered farms	22,781	3,956	8,292	35,029
Rate of current practice	1.30%	0.60%	3.78%	
Number of farms that need to inspect	22,485	3,932	7,979	34,396
Hours to inspect	4.00	4.00	8.00	
Farm operator wage rate	\$72.12	\$72.12	\$42.74	
Annual cost of inspection per farm	\$288.48	\$288.48	\$341.92	
Total annual cost of inspection	\$6,486,429	\$1,134,380	\$2,728,030	\$10,348,838

We estimate the cost of sampling and testing untreated surface water for covered farms when the water is used in a direct application method during growing of covered produce (other than sprouts), in accordance with § 112.46(b). We estimate that 42 percent of irrigated farms use untreated surface water for the relevant purpose (direct water application during growing produce other than sprouts) (Ref. 40). This results in 7,703 very small farms, 1,512 small farms, and 3,339 large farms that must conduct untreated surface water testing. We estimate that the cost of collecting a water sample, including collection, shipping costs, analysis, and travel is \$110. In the initial two years of sampling, we estimate that farms will collect 10 samples annually to develop a microbial water quality profile, and then collect five samples annually to update their microbial water quality profile using a 20-sample rolling dataset (see § 112.46(b)(1)(i)(A) and

(b)(2)(i)(A)) at a per farm cost of \$550 (five samples at \$110 each). Additionally, it may be necessary for farms to take a total of 20 new samples starting in any given year to develop a new water quality profile, if the farm has determined or has reason to believe that its microbial water quality profile no longer represents the quality of its water, in accordance with § 112.46(b)(3)(i)(A). We estimate that 7.5 percent of farms using untreated surface water will need to take 20 new samples starting in any given year to develop a new water quality profile.

Table 15 presents the total costs of testing untreated surface water used for the relevant purpose. We estimate that the total costs of testing surface water are \$7.9 million for very small farms, \$1.6 million for small farms, and \$3.4 million for large firms, totaling to \$12.9 million. These estimates are from the PRIA (Ref. 6) with the exception of the testing frequency which we have updated in finalizing the rule.

Table 15. Costs of Sampling and Testing Untreated Surface Water used in Direct Application During Growing Produce (Other than Sprouts).

Very small Small Total Large 18,262 3,585 7,916 Number of irrigated farms 29,763 42.18% 42.18% 42.18% Percent of farms that use surface water Number of farms that must perform initial 7,703 1,512 3,339 12,554 survey Cost of collecting sample \$110.00 \$110.00 \$110.00 Baseline survey testing frequency* \$550.00 \$550.00 Annually recurring cost of 5 tests \$550.00 Percent of farms that will need to develop new water quality profile 7.5% 7.5% 7.5% Testing frequency (20 samples - 5 already 15 15 15 estimated for all farms) Cost of 20 annual sample testing for 7.5% \$3,013,230 \$591,525 \$1,306,140 \$4,910,895 of farms Cost of 5 annual sample testing for all farms \$4,927,653 \$967,344 \$2,135,982 \$8,030,978 Total cost of sampling and testing \$7,940,883 \$1,558,869 \$12,941,873 untreated surface water \$3,442,122

Note: The initial survey of 20 samples must be in place before farms can comply with some of the other annual requirements for agricultural water that relate to the microbial water quality profile developed from the initial survey. For untreated surface water, testing for this will begin in year 3 for large farms, year 4 for small farms, and year 5 for very small farms.

We estimate the cost of sampling and testing untreated groundwater for covered farms when the water is used in a direct application method during growing of covered produce (other than sprouts), in accordance with § 112.46(b). Assuming that 32 percent of covered farms use groundwater for the relevant purpose (direct water application during growing produce other than sprouts) (Ref. 40), 5,811 very small farms, 1,141 small farms, and 2,519 large farms must test their untreated groundwater. We estimate that the cost of collecting a water sample is \$110 and in the first year, all farms will collect four samples (see § 112.46(b)(1)(i)(B)), at a cost of \$440 per farm. In subsequent years, most farms will collect one sample annually (see § 112.46(b)(2)(i)(B)), at a cost of \$110 per farm per year. Additionally, it may be necessary for farms to take a total of 4 new samples in any given year to develop a new water quality profile, if the farm has determined or has reason to believe that its microbial water quality profile no longer represents the quality of its water, in accordance with § 112.46(b)(3)(i)(B). We estimate that 5 percent of farms using untreated ground water will need to collect four new samples in any given year to develop a new water quality profile. Table 15 presents the costs of testing untreated groundwater used for the relevant purpose. We estimate that the total costs of testing groundwater are \$1.3 million for very small farms, \$246 thousand for small farms, and \$542 thousand for large farms, totaling to \$2.0 million.

Table 16. Costs of sampling and testing untreated groundwater used in Direct Application During Growing Produce (Other than Sprouts)

	Very small	Small	Large	Total
Number of irrigated farms	18,262	3,585	7.916	29,763
Percent of farms that use ground water	31.82%	31.82%	31.82%	31.82%
Number of farms that must test	5,811	1,141	2,519	9,471
Initial testing frequency	. 4	4	4	

Initial testing cost (year 1)	\$440.00	\$440.00	\$440.00	
Annual testing frequency	1	1	1	
Annual testing cost	\$110.00	\$110.00	\$110.00	
Percent of farms that will need to develop new water quality profile	5%	5%	5%	
Testing frequency (4 samples – 1 already estimated for all farms)	3	3	3	
NPV (at 3%)	\$1,259	\$1,259	\$1,259	
NPV (at 7%)	\$1,081	\$1,081	\$1,081	
Annualized costs (at 3%)	\$148	\$148	\$148	
Annualized costs (at 7%)	\$154	\$154	\$154	
Cost of testing for farms testing 4 times per growing season or year	\$401,764	\$78,870	\$174,152	\$654,786
Cost of testing for farms testing once annually	\$849,652	\$166,795	\$368,297	\$1,384,744
Total cost of testing ground water	\$1,251,416	\$245,665	\$542,449	\$2,039,530

We estimate the cost of sampling and testing untreated ground water when used for certain uses specified in § 112.44(a) (including, for example, water used as sprout irrigation water, and water applied in a manner that directly contacts covered produce or food-contact surfaces during or after harvest), in accordance with § 112.46(c). All covered farms and sprouting operations that use untreated ground water for such purposes (i.e., farms that do not use water exempt from testing under § 112.46(a) such as public (e.g., municipal) water sources meeting the established criteria in that section or water treated in accordance with the requirements of § 112.43) must conduct water sampling and testing. We estimate that 41 percent of sprouting operations use untreated ground water for sprout irrigation, and that 30 very small, 25 small, and 62 large sprouting operations must therefore test their untreated groundwater in accordance with § 112.46(c). We estimate that 32 percent of farms use ground water for other purposes identified in § 112.44(a) (other than sprout irrigation water) and 26 percent of these farms use water exempt from testing under § 112.46(a), and 1.3 percent of very small farms, 0.6 percent of small farms, and 3.8 percent of large farms are already conducting water sampling and

testing (20;Ref. 40). The remaining proportion of non-sprout farms and sprouting operations includes 5,292 very small farms, 942 small farms, and 1,896 large farms. We estimate that the cost of collecting and testing a water sample is \$110 and that all farms required to conduct these tests will test an average of 1.5 times per year (the midpoint between 1 and 2 samples). This estimated average is derived from the required testing frequency in § 112.46(c), which requires at least 4 tests in the first year, allowing one test per year thereafter if the results meet the quality criterion, with required resumption of 4 tests per year if any annual test fails to meet the quality criterion. Table 17 presents the total costs of water sampling and testing for farms that use water for § 112.44(a)activities. We estimate that the total costs of water sampling and testing are \$873 thousand for very small farms, \$155 thousand for small farms, and \$313 thousand for large farms, totaling to \$1.3 million.

Table 17. Cost of sampling and testing untreated ground water for § 112.44(a)

purposes

	Very small	Small	Large	Total
Total number of farms	22,781	3,956	8,292	35,029
Number of sprout operations that use untreated ground water	30	25	62	117
Total number of farms	22,811	3,981	8,354	35,146
Percent of non-sprout farms that use ground water	31.82%	31.82%	31.82%	
Number of non-sprout farms that use ground water	7,279	1,283	2,700	
Rate of practice for water treatment	1.30%	0.60%	3.78%	
Percent of farms using public water	26.0%	26.0%	26.0%	
Number of farms that must test under the rule	5,292	942	1,896	
Testing frequency	1.5	1.5	1.5	
Testing cost	\$110.00	\$110.00	\$110.00	
Total costs of water sampling and testing	\$873,183	\$155,432	\$312,879	\$1,341,495

All covered irrigated farms that do not use public water sources exempt from testing and that use water for purposes in § 112.44(b) may choose to conduct water treatment to meet the microbial quality criteria (see § 112.45(b)(3)). Treatment of water is one of multiple options provided in § 112.45(b) to meet the microbial quality criteria in § 112.44(b). Farms may use the option to treat water, for example, if the farm is not able to take advantage of the provisions for microbial die-off and/or microbial removal, provided in § 112.45(b)(1), or the provision for re-inspection and corrections in § 112.45(b)(2). We estimate 22,025 farms (or 74 percent of covered irrigated farms) will conduct testing. We also estimate that 48 percent of irrigated farms use application methods where the water is intended to contact covered produce and 33 percent use application methods where the water is likely to contact covered produce; these include farms growing commodities such as cantaloupe, honeydew, other melons (including Canary, Crenshaw and Persian), pineapple, strawberries, summer squash (such as patty pan, yellow and zucchini), and watermelon (10;Ref. 15;40). We calculate the number of farms that use direct water application methods by adding the proportions and multiplying by the number of farms that must conduct testing, and estimate that this includes 10,946 very small farms, 2,149 small farms, and 4,745 large farms, or 17,840 farms in total. We divide the number of operating days per year across farm size by 360 and multiply this proportion by the average number of irrigated acres for very small, small, and large farms and estimate that there are 122,817 irrigated acres for very small, 131,080 irrigated acres for small, and 2,746,960 irrigated acres for large farms. We estimate that 2.4 percent of irrigated acres do not meet the microbial quality criteria (Ref. 6) and that approximately 80 percent of all farms can use the die-off provisions in §

112.45(b)(1) or the re-inspection and correction provisions in § 112.45(b)(2), leaving 590 acres on very small farms, 629 acres on small farms, and 13,185 acres on large farms that may treat their water to meet the microbial quality criteria. We estimate there to be 2.16 acre-feet of water per acre and multiply (Ref. 40) this by the number of acres to be treated, resulting in 1,273 acre-feet for very small farms, 1,359 acre-feet for small farms, and 28,480 acre-feet for large farms. We estimate that the current rate of practice for water treatment is 1.3 percent for very small farms, 0.6 percent for small farms, and 3.8 percent for large farms, resulting in 1,257 acres on very small farms, 1,351 acres on small farms, and 27,404, acres on large farms to be treated (Ref. 20) We multiply acres by our estimated treatment costs per acre-foot (\$543 for very small farms, \$289 for small farms, and \$32 for large firms) to find total costs. Table 18 presents total costs of water treatment to meet the microbial quality criteria. We estimate that the total costs of treatment are \$682,449 for very small farms, \$390,405 for small farms, and \$876,925 for large farms, totaling to \$1,949,779.

Table 18. Water treatment to meet microbial quality criteria of GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL

	Very small	Small	Large	Total
Number of covered irrigated farms	18,262	3,585	77,916	29,763
Percent of farms that use public water	26%	26%	26%	
Number of farms that test water	13,514	2,653	5,858	22,025
Percent of farms using agricultural water intended to contact covered produce	48%	48%	48%	
Percent of farms using agricultural water likely to contact covered produce	33%	33%	33%	
Number of farms using direct water application	10,946	2,149	4,745	17,840
Percent of season when produce is present	33%	50%	83%	
Farms with irrigated acreage using direct water application methods, weighted by percentage of season when produce is present	3,612	1,074	3,952	8,639
Average irrigated acres	34	122	695	
Irrigated acres using direct water application	122,817			

methods		131,080	2,746,960	
Percent of farms that do not meet quality criteria	2.4%	2.4%	2.4%	
Acres to be treated	2,948	3,146	65,927	
Percent where die-off until harvest or storage is an option	80%	80%	80%	
Acres that must be treated	590	629	13,185	
Acre-ft of water per acre	2.16	2.16	2.16	
Acre-ft of water to be treated	1,273	1,359	28,480	
Rate of current practice	1.3%	0.6%	3.8%	·
Acres that will treat	1,257	1,351	27,404	
Treatment costs per acre-ft	\$543	\$289	\$32	
Total cost	\$682,449	\$390,405	\$876,925	\$1,949,779

All covered farms that use water for purposes in § 112.44(a) that is not public water exempt from testing may choose to conduct water treatment to meet the microbial quality criterion. Treatment of water is one of multiple options provided in § 112.45(a) to meet the microbial quality criterion in § 112.44(a) (see § 112.45(a)(1)(ii)). Farms may use the option to treat water, for example, if the farm is not able to take advantage of the provisions for re-inspection and corrections in § 112.45(a)(1)(i). We estimate that 15.2 percent of water does not meet quality criteria of no detectable E. coli (6;10;20;40;Ref. 41) The number of farms requiring treatment is calculated by multiplying the number of farms using water for § 112.44(a) purposes by the percent of farms that do not meet quality criteria and by the portion of farms that do not use public water exempt from testing. This yields 2,534 very small farms, 446 small farms, and 906 large farms that may treat. We estimate that one-time capital costs will be \$2,441.34 for very small farms, \$3,678.13 for small farms, and \$3,567.78 for large farms and that annual operating costs will be \$117 for very small farms, \$1,099 for small farms, and \$6,714 for large farms(Ref. 6;41;42;43) We add annualized one-time capital costs and annual operating costs and multiply by the number of farms that initially test and then treat water to estimate total

costs of \$1.2 million for very small farms, \$724 thousand for small farms, and \$6.5 million for large farms, totaling to \$8.4 million. Table 19 presents the total costs of water treatment to meet the microbial quality requirement in § 112.44(a).

Table 19. Water treatment to meet quality criterion of no detectable E. coli for

	Very small	Small	Large	<u>Total</u>
Number of covered farms	22,781	3,956	8,292	35,029
Percent of farms using public water	26.0%	26.0%	26.0%	
Number of sprout operations that use untreated ground water	30	25	62	117
Number of farms subject to microbial testing requirements in § 112.46(c) (to meet § 112.44(a) criterion)	16,888	2,952	6,198	26,038
Percent contaminated	15.2%	15.2%	15.2%	
Number of farms that require treatment	2,567	449	942	3,958
Current rate of practice	1.3%	0.6%	3.8%	
Number of farms that test	2,534	446	906	3,886
One-time capital costs	\$2,441.34	\$3,678.13	\$3,567.78	
Annualized costs (3%)	\$286.20	\$431.19	\$418.25	
Annualized costs (7%)	\$347.59	\$523.68	\$507.97	
Operating cost per year	\$117.26	\$1,099.32	\$6,713.74	
Total costs for water treatment	\$1,177,771	\$723,886	\$6,546,385	\$8,448,015

Table 20 presents a summary of the costs of the agricultural water provisions. Excluding recordkeeping, the total cost of the water provisions is \$18 million for very small farms, \$4 million for small farms, and \$14 million for large farms, totaling to \$37 million.

Table 20. Summary of the costs of the agricultural water provisions (in thousands)

Description	Very small	Small	Large	Total
Inspection and maintenance of agricultural water systems	\$6,486	\$1,134	\$2,728	\$10,349
Cost of testing untreated surface water used in direct application during growing for produce other than sprouts	\$7,941	\$1,559	\$3,442	\$12,942
Cost of testing untreated ground water used in direct application during growing for produce other than sprouts	\$1,251	\$246	\$542	\$2,040
Cost of testing untreated ground water used for 112.44(a) purposes (including sprout irrigation water)	\$873	\$155	\$313	\$1,341

Water treatment to meet criteria of GM of 126 CFU / 100 mL or STV of 410 CFU / 100 mL for direct application during growing of produce other than sprouts	\$682	\$390	\$877	\$1,950
Treatment to meet criteria of no detectable E. coli for 112.44(a) purposes, including sprout irrigation water	\$1,178	\$724	\$6,546	\$8,448
Total cost by size category	\$18,412	\$4,209	\$14,449	\$37,070
Cost per farm	\$808	\$1,064	\$1,742	\$1,058

4. Biological Soil Amendments (Subpart F)

The minimum application intervals for biological soil amendments of animal origin, which we proposed in the 2013 proposed rule, have been removed from the rule. We estimate that removing these application intervals will remove an overwhelming majority of all costs originally estimated. Therefore, we have eliminated the original costs estimates attributed to Biological Soil Amendments of animal origin attributable to this rulemaking. There are still recordkeeping requirements related to Biological Soil Amendments, and those costs are presented in the Recordkeeping (Subpart O) section of this analysis.

In addition, the use of Biological Soil Amendment of Animal Origin in growing covered root crops is prohibited unless the amendment meets the requirements of 112.55(a). Therefore, the costs of root crop farms that use BSA of animal origin switching to permissible soil amendments are presented in Table 21. Using data from the NASS Agricultural Census, we estimate that approximately eight percent of covered farms grow root crops (Ref. 15), and 15 percent of total farms apply any type of BSA (Ref. 6;20). Therefore, we estimate that 273 very small farms (22,781 farms x 8 percent x 15 percent), 47 small farms (3,956 farms x 8 percent x 15 percent), and 100 large farms

(8,292 farms x 8 percent x 15 percent) will incur a cost of switching amendment types. From the PRIA, we estimate that the average cost of switching to commercial chemically treated compost is \$1,600 for very small farms, \$6,600 for small farms, and \$17,300 for large farms, and we expect that a switch to permissible amendments for covered root crops (such as amendments not containing materials of animal origin, or BSAs treated to meet the § 112.55(a) microbial standard) will represent a comparable cost. In total, we estimated that the cost of switching away from most BSAs for root crops is approximately \$2.5 million, annually.

Table 21. Cost to root crop farms of switching from compost or raw manure of animal origin

	Very small	Small	Large	Total
Number of farms	22,781	3,956	8,292	35,029
Percent of farms that grow root crops	8%	8%	8%	
Number of root crop farms	1,822	316	663	2,802
Percent of farms using biological soil amendments of any type	15%	15%	15%	
Number of root crop farms using biological soil amendments	273	47	100	420
Average cost of switching to treated BSAs that meet the microbial standard in § 112.55(a) or other permissible amendments	\$1,600	\$6,600	\$17,300	
Total cost by category	\$437,395	'\$313,315	\$1,721,419	\$2,472,130

5. Domesticated and Wild Animals (Subpart I)

We did not receive substantial comments on cost estimates for Domesticated and Wild Animals; therefore, we have not altered the underlying methodology from those

⁸ We recognize that there may be more efficient means of meeting the requirements for an individual farm, such as chemical treatment or switching to a vegetative manure source; however, either of these activities would likely be utilized as a cost savings measure if they are employed instead of purchasing commercial compost. Therefore, our average costs estimates may be viewed as somewhat higher than those that are likely to be realized by individual farms.

⁹ Costs are calculated without taking into account opportunity or time costs of searching for new suppliers or rewriting contracts.

originally proposed and estimated in the PRIA. The rule's requirements have been altered in two key ways that reduce the cost estimated for Domesticated and Wild Animals. First, assessment requirements have been limited to only operational days where the harvestable portion of the product is present. This is a reduction from year round monitoring estimated in the PRIA. Additionally the waiting period requirement related to grazing animals has been removed completely from the rule and thus all of the associated costs have been removed. Table 22 provides the total cost for Domesticated and Wild Animals; for full information on how these costs are estimated please refer to Tables 82 – 83 of the original PRIA (Ref. 6).

Table 22. Cost for Domesticated and Wild Animals

	Very small	Small	Large	Total
Number of produce farms	22,781	3,956	8,292	35,029
Per-acre monitoring cost increase	3.36	3.36	3.36	
Increase in cost per affected farm	\$378	\$1,260	\$2,520	
Percent of year in operation	27%	41%	55%	
Total cost per category	\$2,359,238	\$2,048,449	\$11,449,775	\$15,857,462

6. Growing, Harvesting, Packing, and Holding Activities (Subpart K)

We did not receive substantial comments on the cost estimates for Growing,
Harvesting, Packing, and Holding Activities; therefore, we have not altered the
underlying methodology from those originally proposed and estimated in the PRIA. In
addition, our changes to the proposed requirements in finalizing subpart K do not affect
our cost estimates. Thus, we present the estimates utilizing more current wage
information and farm counts. Table 23 provides the total cost for Growing, Harvesting,
Packing, and Holding Activities. These requirements are reliant on labor hours so the
increase in wage rates has increased the costs. Additionally, based on public comments
we have revised the number of operational days upwards to 100 for very small farms, 150

for small farms, and 200 for large farms (up from 45, 45, and 90), which increases the estimated costs. Finally, in the PRIA we estimated that only farms with post-harvest activities would incur costs of Growing, Harvesting, Packing, and Holding Activities; however, we now estimate that all farms with reusable food contact surfaces will need to clean and sanitize. All of these changes have substantially increased the cost estimates of Growing, Harvesting, Packing, and Holding Activities.

Table 23. Cost of Cleaning and Sanitizing Food Contact Surfaces

	Very small	Small	Large	Total
Number of Farms	22,781	3,956	8,292	35,029
Percentage of farms with reusable food contact surfaces	18%	18%	18%	
Number of farms with reusable food contact surfaces	4,101	712	1,493	
Percentage of farms that do not clean/sanitize food contact surface	30%	30%	30%	
Number of farms that need to clean/sanitize food contact surface	2,870	498	1,045	
Time to clean/sanitize (hours)	0.17	0.25	0.25	
Non-supervisor wages	\$18.56	\$18.56	\$18.56	
Labor cost to clean/sanitize a food contact surface	\$3.16	\$4.64	\$4.64	
Cost of sanitizer per farm job	\$0.05	\$0.05	\$0.05	
Daily per farm cost to clean/sanitize	\$3.21	\$4.69	\$4.69	
Operational harvest days	100	150	200	
Annual per farm cost to clean/sanitize food contact surfaces	\$321	\$704	\$938	
Total cost to clean/sanitize food contact surfaces	\$920,023	\$350,664	\$980,015	\$2,250,701

7. Equipment, Tools, Buildings, and Sanitation (Subpart L)

We did not receive substantial comments on cost estimates for Equipment, Tools, Buildings, and Sanitation requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart L do not affect our cost estimates. Thus, we present only summary statistics of estimates utilizing more current

wage information, farm counts, and operational days where the harvested or harvestable portion of produce is exposed. Table 24 provides the total cost for Equipment, Tools, Buildings, and Sanitation; for full information on how these costs are estimated please refer to Tables 88 – 94 of the original PRIA (Ref. 6). These requirements are almost exclusively reliant on labor hours so the increase in wage rates has increased the costs. Additionally, based on public comments we have revised the number of operational days upwards to 100 for very small farms, 150 for small farms, and 200 for large farms (up from 45, 45, and 90), which greatly increases the costs of these sections.

Table 24. Summary of Equipment, Tools, Buildings, and Sanitation Costs (in Millions)

	Very small	Small	Large	Total
Total cost to clean and sanitize tools	\$5.44	\$6.27	\$22.86	\$34.57
Total cost to clean machinery	\$7.15	\$3.39	\$24.22	\$34.76
Total cost of pest control	\$0.75	\$0.51	\$1.07	\$2.33
Total cost to provide toilets and hand washing	\$3.05	\$1.05	\$12.25	\$16.34
Total cost to prevent sewage contamination	\$0.01	\$0.00	\$0.02	\$0.03
Total cost to dispose litter and land drainage	\$3.09	\$2.69	\$24.88	\$30.66
Total cost of trash removal	\$0.06	\$0.02	\$0.04	\$0.11
Total costs of equipment, tools, buildings, and sanitation	\$19.49	\$13.91	\$85.29	\$118.69

8. Sprouts (Subpart M)

We did not receive substantial comments on cost estimates for Sprouts requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart M do not affect our cost estimates related to subpart M, other than those captured in other parts of this document. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 26

provides the total cost for Sprouts; for full information on how these costs are estimated please refer to Tables 102 - 107 of the original PRIA (Ref. 6).

Table 25 presents updated costs to conduct batch tests related to sprouts. The initial estimate has not changed substantially from those presented in the PRIA. We estimate that it costs approximately \$147 to test each batch of sprouts for E. Coli O157:H7 and Salmonella, and there are approximately 3,710 batches from the 74 very small sprouting operations, 2,976 batches from the 60 small sprouting operations, and 33,623 batches from the 151 large sprouting operations. We estimate that batch testing for E. Coli O157:H7 and Salmonella will cost approximately \$5 million, annually. New language has been added to the rule which requires sprouting operations to hold their batches while awaiting the test results. We estimate holding costs as a function of the total value of sprouts produced by the operation. We estimated that very small sprouting operations generate total revenue of \$70 thousand annually, small sprouting operations generate revenue of \$300 thousand annually, and large sprouting operations generate annual revenue of approximately \$600 thousand annually (Ref. 44). We estimate that very small operations will need to hold 25 percent of their product while awaiting test results, small operations will hold 10 percent of their product, and large operations will only need to hold 5 percent of their product. Additionally, commonly cited holding costs in the manufacturing literature are 25% of the total value. This yields an annual holding cost for very small sprouting operations of \$43,750 (\$70 thousand x .25 x .25), small operations of \$7,500 (\$300 thousand x .10 x .25), and large operations of \$30,000 (\$600 thousand x .05 x .1), and a total estimate of approximately \$81 thousand. There is also a requirement that sprout operations take appropriate action to prevent any food that is

adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (Ref. 44) from entering commerce; however, we do not estimate any additional costs to this language as any such product is already illegal to sell. Finally, we add 10 percent on to the bottom line to account for language which requires batch testing for additional pathogens if and when certain criteria are met. In total we estimate that batch testing of sprouts will cost approximately \$5 million dollars annually.

Table 25. Total costs to test each batch of sprouts for E. coli O157:H7, Salmonella

species, and additional pathogens as applicable

	Very small	Small	Large	Total
Number of sprouting operations	74	60	151	285
Number of batches	3,710	2,976	33,623	
Testing costs	\$545,444	\$437,532	\$4,943,253	
Rate of industry practice	55%	55%	55%	
Total cost by size category	\$245,450	\$196,889	\$2,224,464	\$2,666,803
Average Sales Volume	\$70,000	\$300,000	\$600,000	
Inventory Holding Cost	25%	25%	25%	
Additional Holding Time	14%	14%	14%	
Per Facility Cost of Holding Product Awaiting Test Results	\$2,500	\$10,714	\$21,429	
Rate of industry practice	55%	55%	55%	
Total Cost of Holding Product Awaiting Test Results	\$83,250	\$289,286	\$1,456,071	\$1,828,607
Percent needing to be held	25%	10%	5%	
Inventory Holding Cost	25%	25%	25%	
Inventory Holding Cost	\$323,750	\$450,000	\$1,132,500	\$1,906,250
Addition for additional pathogen testing costs	10%	10%	10%	
Additional pathogen testing costs	\$56,920	\$64,689	\$335,696	\$457,305
Total cost of E. coli O157:H7 and Salmonella batch testing, holding, prevention, and additional pathogen tests	\$626,120	\$711,578	\$3,692,660	\$5,030,358

There are new requirements for sprout producers to establish a written corrective action plans as part of their environmental monitoring plan and written sampling plans; however, these costs are presented in the recordkeeping section of this analysis rather than the sprout requirements.

Table 26. Summary of the Total Costs of the Sprouts Provisions

	Very small	Small	Large	Total
Costs to disinfect seeds	\$79,190	\$63,523	\$717,683	\$860,396
Costs to implement an environmental monitoring plan	\$117,957	\$164,759	\$588,495	\$871,212
Costs for a specified protocol for collecting environmental samples and testing for L. sp., or L. monocytogenes	\$795	\$644	\$1,622	\$3,061
Cost of E. coli O157:H7 and Salmonella batch testing, holding, prevention, and additional pathogen tests	\$626,120	\$711,578	\$3,692,660	\$5,030,358
Total costs of the sprouts provisions	\$824,062	\$940,504	\$5,000,461	\$6,765,027

9. Recordkeeping (Subpart O)

Farms will incur recordkeeping costs related to demonstrating qualified exemption status; the commercial processing exemption; the agricultural water provisions; the biological soil amendments of animal origin provisions; cleaning equipment, tools, buildings, and sanitation; sprouting operations; and food safety training. We present detailed costs for the recordkeeping activities required for agricultural water and new provisions for sprouting operations; however, the other records have not changed substantially from the PRIA (though there have been some changes to recordkeeping, discussed in greater detail in the Paperwork Reduction Act analysis), and we therefore present in this section only summary statistics of the remainder of recordkeeping activities. For more on the full methodology please refer to the PRIA (Ref. 6).

We estimate that farms will incur recordkeeping costs pertaining to the water provisions (under Subpart O and § 112.50), including keeping records of inspection of water systems (§ 112.50(b)(1)), test results of untreated surface water (§ 112.50(b)(2)), test results of untreated ground water (§ 112.50(b)(2)), scientific information supporting adequacy of water treatment methods (§ 112.50(b)(3)), water treatment monitoring results (§ 112.50(b)(4)), documentation of corrective actions including use of microbial

die-off or removal rates (§ 112.50(b)(6)) and scientific data relied on for such rates between harvest and end of storage (§ 112.50(b)(5)), use of public water sources (§ 112.50(b)(7)), data to support any alternatives (including alternative microbial quality criteria, alternative microbial die-off rates and maximum time intervals, or alternative minimum numbers of samples for initial and annual surveys in testing untreated water used for direct water application in growing produce other than sprouts) (§ 112.50(b)(8)), and analytical methods used in lieu of those incorporated in the rule (§ 112.50(b)(9)).

We estimate that all covered farms not currently keeping such records will maintain records of inspection of water systems (§ 112.50(b)(1)) and that the time burden is one hour annually. We multiply the farm operator wage rate by the time burden and annual frequency and estimate the costs of water inspection records are \$1.6 million for very small farms, \$284 thousand for small farms, and \$341 thousand for large farms.

From earlier estimates of water testing, we estimate that there are a total of 26,038 farms that use untreated ground water will incur the costs maintaining records of their results from testing the water for 0 detectable generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is estimated to be 2 times. We multiply the farm operator wage rate by the time burden and the annual frequency and estimate the costs of surface water testing records are \$804 thousand for very small farms, \$141 thousand for small farms, and \$175 thousand for large farms.

From earlier estimates of water testing, we estimate that 12,544 farms (those that use untreated surface water less the percentage estimated to use public water sources) will incur costs maintaining records of their results from testing the water for GM of 126

CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is estimated to be 10 times in the first two years and 5 times in subsequent years. We multiply the farm operator wage rate by the time burden and the net present value of the annual frequency over ten years and estimate the costs of surface water testing records are \$1.2 million for very small farms, \$226 thousand for small farms, and \$296 thousand for large farms.

From earlier estimates of water testing, we estimate that 9,471 farms (those that use untreated ground water less the percentage estimated to use public water sources) will incur costs maintaining records of results from testing the water for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is 4 times in the first year and once in subsequent years. We multiply that farm operator wage rate by the time burden and the net present value of the annual frequency over ten years and estimate the costs of ground water testing records \$194 thousand for very small farms, \$38 thousand for small farms, and \$50 thousand for large farms.

We estimate that 20 percent of farms that treat water to meet quality criteria of GM of 126 CFU / 100ml or STV of 410 CFU / 100ml and 50 percent of farms that treat water to meet quality criterion of no detectable E. coli (a total of 5,547 farms) will maintain records of the adequacy of their water treatment methods (§ 112.50(b)(3)). We estimate that 5,547 will maintain records, with a one-time burden of 0.5 hours. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and

stimate that the costs of maintaining records of data to support method adequacy are \$194 thousand for very small farms, \$38 thousand for small farms, and \$50 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

From earlier estimates of water testing, we estimate that all farms that treat their water (an estimated total of 5,547 farms) will maintain records of the results of water treatment monitoring (§ 112.50(b)(4)), with an annual time burden of one hour. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and the annual frequency and estimate that the costs of maintaining records of water treatment monitoring are \$250 thousand for very small farms, \$47 thousand for small farms, and \$61 thousand for large farms.

Farms that rely on a microbial die-off or removal rate to determine a time interval between harvest and end of storage, including other activities such as commercial washing, to achieve a calculated log reduction of generic E. coli in accordance with § 112.45(b)(1)(ii), must have documentation of the scientific data or information they rely on to support that rate (§ 112.50(b)(5)). We estimate that 25 percent of all farms that rely on die-off, 3,661 (17,840 farms from table 18 of the FRIA x 80 percent that rely on die off + 371 irrigated farms subject to a corrective action x 25 percent) would generate these records for postharvest die-off intervals. It is estimated that two recordkeepers for each of 3,661 farms will spend .5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and estimate that the costs of maintaining records of data to support microbial die-off are

\$162 thousand for very small farms, \$32 thousand for small farms, and \$41 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

When covered farms take corrective actions in accordance with § 112.45, they must maintain certain required records (§ 112.50(b)(6)), including keeping certain records about specific time intervals or log reductions applied. We calculate that 14,643 farms will incur the costs of documentation of any corrective actions taken in accordance with § 112.45, including any time intervals or calculated log reductions applied.

Therefore, it is estimated that 1 recordkeeper on each of the 14,643 farms will spend an average of 0.5 hours per year on recordkeeping related to corrective actions applied. The total costs of corrective action recordkeeping, including microbial die-off or removal records, is \$325 thousand for very small farms, \$63 thousand for small farms, and \$83 thousand for large farms.

All covered farms that use public water sources exempt from testing, such as municipal water, will maintain certain required records related to those public water systems (§ 112.50(b)(7)). We estimate that 9,108 farms (the number of farms using public water systems such as municipal water sources) will need to keep these records and that the time burden is 0.33 hours annually (Ref. 6;10;40) We multiply the farm operator wage by the proportion of farms that use municipal water and estimate that public water system recordkeeping costs are \$141 thousand for very small farms, \$24 thousand for small farms, and \$30 thousand for large farms.

Section 112.50(b)(8) requires all farms that choose to rely on an alternative under § 112.49 to have documentation of the scientific data or information they rely on to

support that alternative. There are four types of alternatives that may be employed according to 112.49(a)-(d).

Section 112.49(a) provides for an alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b). Farms must maintain records supporting any such alternative microbial criteria they use (§ 112.50(b)(8)). We estimate that approximately 8,757 farms that irrigate (35,029 total farms x 25 percent) will generate these alternative records. We estimate each farm will spend half an hour one time on this documentation. We multiply the farm operator wage by the number of farms and estimate that this alternative microbial quality criterion recordkeeping costs are \$205 thousand for very small farms, \$36 thousand for small farms, and \$44 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(b) provides for an alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i). Farms must maintain records supporting any such alternative die off rate and maximum time interval they use (§ 112.50(b)(8)). We estimate that approximately 3,661 farms that irrigate (14,643 total farms x 25 percent) will generate these alternative records. We estimate each farm will spend half an hour one time on this documentation. We multiply the farm operator wage by the number of farms and estimate that this alternative microbial die-off rate recordkeeping costs are \$81 thousand for very small farms, \$16 thousand for small farms, and \$21 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(c) provides for an alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A). Farms must maintain records supporting any such alternative sampling rate they use (§ 112.50(b)(8)). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources x 20 percent) will generate these alternative records. We estimate that 1,541 very small farms, 302 small farms, and 668 large farms will develop one record that will take 0.5 hours to complete. In total, we estimate that this recordkeeping will cost very small farms \$56 thousand, small farms \$11 thousand, and large farms \$14 thousand. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(d) provides for an alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A). Farms must maintain records supporting any such alternative sampling rate they use (§ 112.50(b)(8)). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources x 20 percent) will generate these alternative records. We estimate that 1,541 very small farms, 302 small farms, and 668 large farms will develop one record that will take 0.5 hours to complete. In total, we estimate that this recordkeeping will cost very small farms \$56 thousand, small farms \$11 thousand, and large farms \$14 thousand. Because this is a onetime cost, we then annualize over 10 years.

All farms that are required to test their agricultural water in compliance with § 112.46 must have documentation of any analytical methods that they choose to use for such testing in lieu of the methods that are incorporated by reference in § 112.151 (§ 112.50(b)(9)). It is not known how many farms will use other analytical methods; however, to the extent that they do this it will likely be as a cost savings measure. Therefore, we do not include any cost of recordkeeping for 112.50(b)(9) here. This is acknowledged in the PRA analysis.

Table 27 presents the recordkeeping costs of the water provisions. We estimate that the total costs of recordkeeping are \$4.5 million for very small farms, \$0.83 million for small farms, and \$1.0 million for large farms, totaling to \$6.4 million.

Table 27. Recordkeeping Costs of the Water Provisions

	Very small	Small	Large	Total
Farm operator wages	\$72.12	\$72.12	\$42.74	
Inspection of water systems (§ 112.50(b)(1))				
Number of farms	22,485	3,932	7,979	34,396
Time burden	1	1	1	
Frequency	1	1	1	
Total inspection recordkeeping costs	\$1,621,607	\$283,595	\$341,004	\$2,246,206
Initial and annual tests for 0 detectable Get (§ 112.50(b)(2))	neric E. coli			
Number of farms	16,888	2,952	6,198	26,038
Time burden	2	2	2	
Frequency	0.33	0.33	0.33	
Baseline recordkeeping costs of testing ground water for 0 detectible generic E. coli	\$803,869	\$140,515	\$174,835	\$1,119,219
Initial and annual tests of surface water for Generic E. coli (§ 112.50(b)(2))	r GM of 126 CF	U / 100 mL an	d STV of 410 C	FU / 100 mL
Number of farms	7,703	1,512	3,339	12,554
Time burden	0.33	0.33	0.33	
Frequency	6.29	6.29	6.29	
Baseline recordkeeping costs of testing surface water for GM 126 CFU/STV 410 CFU/100 mL generic E. coli	\$1,153,122	\$226,369	\$296,218	\$1,675,708

Initial and annual tests of ground water for Generic E. coli	GM of 126 CF	U / 100 mL an	d STV of 410 C	CFU / 100 mL
(§ 112.50(b)(2))		.,		
Number of farms	5,811	1,141	2,519	9,471
Time burden	0.33	0.33	0.33	
Frequency	1.4	1:4	1.4	
Baseline recordkeeping costs of testing ground water for GM 126 CFU/STV 410 CFU/100 mL generic E. coli	\$193,618	\$38,009	\$49,737	\$281,365
Cost of records of data to support adequacy (a)(2) (§ 112.50(b)(3))	of a treatment r	method used to	satisfy § 112.4	(3(a)(1) and
Number of farms	3,473	654	1,420	5,547
Time burden	0.5	0.5	0,5	
Frequency	1	1	1	
Recordkeeping costs of data to support method adequacy	\$125,228	\$23,588	\$30,346	179,161
NPV (@7%)	\$17,830	\$3,358	\$4,321	\$25,509
Cost of records of results of water treatment (§ 112.50(b)(4))	monitoring rec	ords		
Number of farms	3,473	654	1,420	5,547
Time burden	1	1	. 1	
Frequency	1	1	. 1	
Recordkeeping costs of water treatment	\$250,455	\$47,175	\$60,692	358,322
NPV (@7%)	\$35,659	\$6,717	\$8,641	\$51,017
Cost of records of data to support microbial or removal during activities such as commer (§ 112.50(b)(5))		ie interval betv	veen harvest an	d end of storage
Number of farms	2,251	440	970	3,661
Time burden	0.5	0.5	0.5	-
Frequency	2	2	2	
Recordkeeping costs of data to support die- off or maximum time interval	\$162,339	\$31,727	\$41,454	° \$235,520
Costs of records for corrective actions under (§ 112.50(b)(6))	§ 112.45, inclu	iding die-off o	r removal ușe	
Number of farms	9,004	1,760	3,880	14,643
Time burden	1	1	1	
Frequency	0.5	0.5	0.5	
Recordkeeping costs for corrective actions, including die-off or removal use	\$324,677	\$63,454	\$82,909	\$471,039
Costs of records related to public water syste (§ 112.50(b)(7))	ms			
Number of covered irrigated farms	5,923	1,029	2,156	9,108
Time burden	0.33	0.33	0.33	
Frequency	1	1	1	

Recordkeeping cost of public water systems	\$140,966	\$24,479	\$30,408	\$195,853
Scientific data or information you rely on to accordance with § 112.49(a) (§ 112.50(b)(8))	support any al	ternative that y	ou establish an	d use in
Number of farms	5,695	989	2,073	8,757
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	\$205,371	\$35,663	\$44,300	\$285,334
NPV (@7%)	\$29,240	\$5,078	\$6,307	\$40,625
Scientific data or information you rely on to accordance with § 112.49(b) (§ 112.50(b)(8))	support any ali	ternative that y	ou establish an	d use in
Number of farms	2,251	440	970	3,661
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	\$81,169	\$15,863	\$20,727	\$117,760
NPV (@7%)	\$11,557	\$2,259	\$2,951	\$16,766
Scientific data or information you rely on to accordance with § 112.49(c) (§ 112.50(b)(8))	support any al	ternative that y	ou establish an	d use in
Number of farms	1,541	302	668	2,511
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	· ·
Recordkeeping cost of data to support alternatives	\$55,553	\$10,906	\$14,271	\$80,730
NPV (@7%)	\$7,910	\$1,553	\$2,032	\$11,494
Scientific data or information you rely on to accordance with § 112.49(d)(§ 112.50(b)(8))		ternative that y	ou establish an	d use in
Number of farms	1,541	302	668	2,511
Time burden	0.5	. 0.5	. 0.5	
Frequency	. 1	1	1	
Recordkeeping cost of data to support alternatives	\$55,553	\$10,906	\$14,271	\$80,730
NPV (@7%)	\$7,910	\$1,553	\$2,032	\$11,494
Total recordkeeping costs of the water provisions	\$4,510,303	\$828,664	\$1,042,849	\$6,381,815

Sprouting operations will incur one-time and recurring recordkeeping costs (Subpart O and § 112.150).

One-time recordkeeping costs include an environmental monitoring plan (§ 112.150(b)(2)) with a one-time burden of 7 hours for very small farms, 12 hours for small firms, and 17 hours for large firms (Ref. 3) not already estimated to be performing these actions. These time burdens are multiplied by the number of sprouting operations and the wage rate for farm operators (\$72.12 for very small and small farms, \$42.74 for large farms) to estimate a total one-time cost of \$123,379.

One-time recordkeeping costs also include an irrigation water sampling plan (§ 112.150(b)(3)) with a one-time burden of 8 hours per sprouting operation not already performing these actions. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate a one-time irrigation water sampling plan recordkeeping cost of \$79,944.

Sprout operations are required to have documentation of any analytical methods used in lieu of the methods for both environmental testing and batch testing that are incorporated by reference in §§ 112.152 and 112.153 (§ 112.150(b)(5)). It is not known how many sprout operations will use other analytical methods; however, to the extent that they do this it will likely be as a cost savings measure. Therefore, we do not include any cost of recordkeeping for 112.50(b)(5) here. This is acknowledged in the PRA analysis. In addition, § 112.144(c) requires sprout operations to conduct testing for additional pathogens when certain conditions are met, and § 112.150(b)(5) requires sprouting operations to have documentation of any analytical methods used for such testing because there is no specific method for such testing incorporated by reference in § 112.152 or 112.153. It is not known if or when there will be a pathogen(s) meeting the relevant criteria; however, it is estimated that one 2 hour record will fulfill this requirement,

estimated as the time needed to establish a new testing routine. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate a one-time record of analytical testing method recordkeeping cost of \$19,986.

One-time environmental monitoring plan, irrigation water sampling plan, and additional pathogen analytical test method recordkeeping costs total to \$56,251 for very small operations, \$59,023 for small operations, and \$108,036 for large operations. Table 28 presents these totals annualized at 7 percent for 10 years, estimated at \$8,009 for very small operations, \$8,404 for small operations, and \$15,382 for large operations, totaling to \$31,794.

Table 28. One-time Recordkeeping Costs for Sprouts

One-time recordkeeping costs	Very small operations	Small Operations	Large Operations	Total
Environmental monitoring plan (§ 112.15)	0(b)(2))			
Number of sprout operations	46	37	94	177
Time burden	7	12	17	
Frequency	1	1	1	
Recordkeeping cost of environmental monitoring	\$23,162	\$32,194	\$68,022	\$123,379
NPV (@7%)	\$3,298	\$4,584	\$9,685	17,566
Irrigation water sampling plan(§ 112.150((b)(3))			
Number of sprout operations	46	37	94	177
Time burden	8	8	8	
Frequency	1	1	1	
Recordkeeping cost of water sampling plan	\$26,471	\$21,463	\$32,011	\$79,944
NPV (@7%)	\$3,769	\$3,056	\$4,558	11,382
Record of analytical method for additional	l pathogen testing	g(§§ 112.150(l)(5), 112.44(c))
Number of sprout operations	46	37	94	177
Time burden	2	2	2	
Frequency	1	1	1	
Recordkeeping cost of analytical method	\$6,618	\$5,366	\$8,003	\$19,986
NPV (@7%)	\$942	\$764	\$1,139	2,846
Total one-time recordkeeping costs by size category	\$56,251	\$59,023	\$108,036	\$223,309
Annualized one-time recordkeeping	\$8,009	\$8,404	\$15,382	\$31,794

costs by size category (7 percent for 10	·		
years)			

We estimate that sprouting operations not already performing certain recordkeeping activities will incur recurring recordkeeping costs, including documentation of seed treatment (§ 112.150(b)(1)), environmental monitoring plan - annual maintenance (§ 112.150(b)(2)), environmental monitoring test results (§ 112.150(b)(4)), spent irrigation water sampling plan – annual maintenance (§ 112.150(b)(3)), spent irrigation water test results (§ 112.150(b)(4)), and documentation of corrective actions taken under §§ 112.142(b) and (c), 112.146, and 112.148 (§ 112.150(b)(6)).

We estimate that records of documentation of seed or bean treatment (including documentation of previous treatment by a third party) ((§ 112.150(b)(1)), will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 50 times for small and very small operations, and 223 times for large operations, based on the number of batches. We estimate that this record will take approximately 12 minutes to make (20 percent of one hour). These time burdens multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual record of seed treatment recordkeeping cost of \$173,015.

Environmental monitoring plan- annual maintenance recordkeeping (§ 112.150(b)(2)) will need to be documented by 177 sprouting operations not already performing these activities. This record will need to be made once annually by each operation. We estimate that this record will take approximately 9 minutes to make (15 percent of one hour). These time burdens are multiplied by the number of sprouting

operations and by the farm operator wage rate to estimate an annual environmental monitoring plan- annual maintenance recordkeeping cost of \$1,499.

Environmental monitoring test result records (§ 112.150(b)(4)) will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 60 times for very small operations, 120 times for small operations, and 180 times for large operations, based on the number of tests conducted. We estimate that this record will take approximately 10 minutes to make (17 percent of one hour). These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual environmental monitoring test result recordkeeping cost of \$153,088.

Spent irrigation water sampling plan – annual maintenance recordkeeping (§ 112.150(b)(3)) will need to be documented by 177 sprouting operations not already performing these activities. This record will need to be made once for each operation. We estimate that this record will take approximately one hour to make. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual spent irrigation water sampling plan – annual maintenance recordkeeping cost of \$9,993.

Spent irrigation water test results records (§ 112.150(b)(4)) will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 125 times for very small and small operations, and 558 times for large operations, based on batches. We estimate that this record will take approximately 9 minutes (15 percent of one hour) to make. These time burdens are

multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual spent irrigation water test results recordkeeping cost of \$324,403.

Documentation of corrective actions taken under §§ 112.142(b) and (c), 112.146, and 112.148 (§ 112.150(b)(6)) will need to be documented by 285 sprouting operations. This record will need to be made once for each corrective action. We estimate that this record will take approximately 30 minutes (50 percent of one hour) to make. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual corrective action recordkeeping cost of \$8,059.

Each of these time burdens is multiplied by the hourly wage rate for farm operators at very small, small, and large operations. Table 29 presents the recurring recordkeeping costs for the sprouts provisions. We estimate the total recurring recordkeeping costs for sprouts are \$100,016 for very small operations, \$100,956 for small operations, and \$469,085 for large operations.

Table 29. Recurring Recordkeeping Costs for Sprouts

Recurring recordkeeping costs	Very small operations	Small Operations	Large Operations	Total		
Documentation of seed treatment	(§ 112.150(b)(1)))				
Number of sprout operations	33	27	68	128		
Time burden	50	50	223			
Frequency	0.20	0.20	0.20			
Recordkeeping cost of seed treatment	\$24,016	\$19,472	\$129,527	\$173,015		
Environmental monitoring plan -	annual maintenan	ce(§ 112.150(b)(2	2))			
Number of sprout operations	46	37	94	177		
Time burden	1	1	1			
Frequency	0.15	0.15	0.15			
Recordkeeping cost of environmental monitoring - annual maintenance	\$496	\$402	\$600	\$1,499		
Environmental monitoring test results(§ 112.150(b)(4))						
Number of sprout operations	33	27	68	128		
Time burden	60	120	180			
Frequency	0.17	0.17	0.17			

Recordkeeping cost of environmental monitoring test results	\$24,496	\$39,724	\$88,868	\$153,088
Spent Irrigation water sampling pla	n –annual mainten	ance(§ 112.150(b))(3))	
Number of sprout operations	46	37	94	177
Time burden	1	1	1	,
Frequency	1	1	1	
Recordkeeping cost of water sampling plan - annual maintenance	\$3,309	\$2,683	\$4,001	\$9,993
Spent irrigation water test results(§	112.150(b)(4))			
Number of sprout operations	33	27	68	128
Time burden	125	125	558	
Frequency	0.15	0.15	0.15	,
Recordkeeping cost of spent irrigation water test results	\$45,030	\$36,511	\$242,862	\$324,403
Recordkeeping costs of corrective a 112.150(b)(6))	ctions taken under	§§ 112.142(b) an	d (c), 112.146, and	112.148 (§
Number of sprout operations	74	60	151	285
Time burden	1	1	1	
Frequency	0.50	0.50	0.50	
Recordkeeping cost of spent irrigation water test results	\$2,668	\$2,164	\$3,227	\$8,059
Total recurring recordkeeping costs by size category	\$100,016	\$100,956	\$469,085	. \$670,057

Table 30 presents a summary of recordkeeping costs. The total costs of recordkeeping are \$16 million for very small farms, \$4.2 million for small farms, and \$7.3 million for large farms, totaling to \$27.5 million for all farms.

Table 30. Summary of Recordkeeping Costs (annually, in thousands)

Recording activity	Very Small	Small	Large	Total
Qualified exempt farms labeling and documentation (§ 112.7)	\$5,239	\$469	\$0	\$5,709
Agricultural water (§ 112.50)	\$4,510	\$829	\$1,043	\$6,382
Biological soil amendments of animal origin (§ 112.60)	\$184	\$32	\$40	\$256
Equipment, tools, buildings, and sanitation (§ 112.140)	\$4,829	\$2,620	\$5,492	\$12,941
Sprouting operations (§ 112.150)	\$108	\$109	\$484	\$702
Training (§ 112.30)	\$1,069	\$186	\$227	\$1,482
Documentation relating to commercial processing exemption	\$13	\$3	\$3	\$18

(§ 112.2(b)(4))				
Total cost (annual in thousands)	\$15,951	\$4,249	\$7,290	\$27,490

10. Administrative Provisions

We did not receive substantial comments on the cost estimates for Administrative Provisions; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing those provisions do not affect our cost estimates. Thus, we present the estimates utilizing more current wage information and farm counts. Table 31 provides the total cost for Administrative Provisions.

In total we estimate that learning about the rule will cost all farms approximately \$23 million, annualized at 7 percent over ten years. These costs are comprised of all qualified exempt and non-covered farms spending 4 hours with the rule, which was lowered from 10 hours estimated in the PRIA based on public comment and feedback from public meetings. Very small covered farms are estimated to spend 40 hours with the rule, and small and large covered farms spend 40 hours with the rule as well as 40 hours of legal review (for a total of 80 hours); these estimates have not been altered from those originally proposed.

Table 31. Total Costs of Reading and Learning about the Rule Requirements

	Exempt	Very Small	Small	Large	Total
Number of qualified exempt and non-covered farms	74,931	30,952	5,128	10,105	121,116
Farm operator wage	\$42.74	\$72.12	\$72.12	\$42.74	
Time reading and learning rule	4	. 4	. 4	4	
Per farm learning cost	\$171	\$288	\$288	\$171	
Cost to learn about the rule	\$12,810,204	\$8,929,032. 96	\$1,479,325	\$1,727,551	
Number of covered farms	0	22,781	3,956	8,292	35,029
Farm Operator Wage		\$72.12	\$72.12	\$42.74	

Time reading and learning rule		40	40	40	
Legal analyst wage			\$96.00	\$96.00	
Time reading and learning rule			40	40	
Per farm learning cost		\$2,885	\$6,725	\$5,550	
Cost to learn about the rule		\$65,718,629	\$26,603,309	\$46,017,283	
Total One Time Cost	\$12,810,204	\$74,647,662	\$28,082,634	\$47,744,834	\$163,285,334
Costs annualized over 10 years	\$1,823,885	\$10,628,148	\$3,998,335	\$6,797,790	\$23,248,158

11. Corrective Steps

Although the requirements have not changed dramatically from those proposed in the original rule, our estimates of Corrective Steps have increased from those originally provided. Primarily in response to comments received on the economic analysis, we have doubled the frequency at which we estimate that corrective actions may occur. Otherwise, we generally retain our costs methodology from those in the PRIA. The analysis include all steps taken under 112.45, for example, when agricultural water is not safe/adequate or fails to meet a microbial standard, and all the steps required in subpart M for sprouters when they get an environmental positive or a batch pathogen positive (required under 112.146 and 148). Our changes to the proposed requirements for corrective actions were in relation to the requirements for agricultural water and sprouts. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 32 provides the total cost for Corrective Steps related to agricultural water and sprouts; for full information on how these costs are estimated please refer to Tables 119 – 120 of the original PRIA(Ref. 6).

Table 32. Summary of Costs of Corrective Steps (in thousands)

	Very Small	Small	Large	Total
Failed standards Directed to Agricultural Water	\$412	\$97	\$260	\$770
Failed standards Directed to Sprouts	\$322	\$336	\$1,818	\$2,476

\$433

12. Variances

We did not receive substantial comments on the cost estimates for Variances; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart P do not substantively affect our cost estimates. Thus, we present the estimates utilizing more current wage information and a slightly increased number of applicants, to account for the allowance for tribal applications. Table 33 provides the total cost for Administrative Provisions.

Table 33. Total Costs of Preparing and Reviewing Initial Petition

	Cost Components	
Hours to complete petition	80	
Wage (GS 14.1)	\$75.62	
Cost to complete petition	\$6,049.60	
Hours to internally review	40	
Wage (GS 15.3)	\$94.88	
Cost to internally review petition	\$3,795.20	
Cost to complete & review	\$9,844.80	
Hours for FDA review	80	
Wage (GS 13.7)	\$76.79	
Cost for FDA review	\$6,143.20	٠
Total individual cost of petition	\$15,988	
Potential number of applicants	7	
Total Cost of Preparing and Reviewing Final Petition	\$111,916	

13. Summary of Costs

The total costs by standard in the rule and other sections are summarized in Table 34 by farm size. The "not covered" category only includes the 74,931 farms that generate an average annual monetary value of produce sold of \$25,000 or less. All farms

either covered or not by the rule would incur the costs to learn the rule. In addition to learning the rule, the 30,952 covered by the rule would incur the costs of implementing the standards directed to personnel health and hygiene; agricultural water; domesticated and wild animals; growing, harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation; personnel qualifications and training; sprouts (only for sprout farms); and recordkeeping.

Farms that are eligible for a qualified exemption would incur costs to not only learn the rule and retain documentation demonstrating their eligibility for the qualified exemption, but also costs to change labels if necessary or otherwise disclose their name and complete business address at the point of sale. For farms that grow, harvest, pack, or hold produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, costs will be incurred in making required disclosures and receiving and maintaining records of written assurances from customers. The costs to these farms of these requirements are included in the total recordkeeping costs of the rule.

The estimates in Table 34 are reported in millions for ease of readability with the exception of the average cost per farm estimates, which are reported with no abbreviation.

Table 34. Summary of Costs for the Produce Safety Rule (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total
Personnel Qualifications and training	\$0.00	\$41.14	\$54.08	\$92.16	\$187.38
Health and Hygiene	\$0.00	\$28.11	\$13.59	\$93.91	\$135.61
Agricultural water	\$0.00	\$18.41	\$4.21	\$14.45	\$37.07
Biological soil amendments of animal origin	\$0.00	\$0.44	\$0.31	\$1.72	\$2.47
Domesticated and wild animals	\$0.00	\$2.36	\$2.05	\$11.45	\$15.86
Growing, harvesting, packing, and holding activities	\$0.00	\$0.92	\$0.35	\$0.98	\$2.25
Equipment, tools, buildings, and	\$0.00	\$19.49	\$13.91	\$85.29	\$118.69

sanitation					
Sprouting operations	\$0.00	\$0.82	\$0.94	\$5.00	\$6.77
Recordkeeping	\$5.71	\$10.71	\$3.78	\$7.29	\$27.49
Administrative cost to learn the rule	\$1.82	\$10.63	\$4.00	\$6.80	\$23.25
Corrective steps	\$0.00	\$0.73	\$0.43	\$2.08	\$3.25
Variances	\$0.00	\$0.00	\$0.00	\$0.11	\$0.11
Total Costs (annual in millions)	\$7.53	\$133.76	\$97.65	\$321.24	\$560.19
Average Cost per farm	\$101	\$5,872	\$24,683	\$38,741	\$15,992

The costs of the rule may decrease over time as farms learn by doing. However, these costs of this rule will not be immediately realized, nor will they be uniformly implemented, due to the staggered nature of compliance times. Table 35 presents the annual estimates of costs as they are estimated to occur.

Table 35. Timing of Produce Costs (in millions)

Farms	Year1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered	Farms									
Very Small	\$0	\$0	\$0	\$0	\$115	\$115	\$133	\$133	\$133	\$133
Small	\$0	\$0	\$0	\$92	\$92	\$97	\$97	\$97	\$97	\$97
Large	\$0	\$0	\$302	\$302	\$316	\$316	\$316	\$316	\$316	\$316
	Covered Sprout operations									
Very Small Sprouts	\$0	\$0	\$0	\$1	\$1	\$1	\$1	\$1	\$1	\$1
Small Sprouts	\$0	\$0	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1
Large Sprouts	\$0	\$5	\$5	\$5	\$5	\$5	\$5	\$5	\$5	\$5
	Exempt Farms									
Very Small Exempt	\$0	\$0	\$ 0	\$0	\$7	\$7	\$7	\$7	\$7	\$7
Small Exempt	\$0	\$0	\$0	\$1	\$1	\$1	\$1	\$1	\$1	\$1
Large Exempt	\$0	\$0	\$0	\$0	\$0	\$0_	\$0_	\$0	\$0	\$0_

Note: Summing across a single year gives a single year cost of full may not match the actually estimated cost of this rulemaking due to rounding errors in this table, which is meant for illustrative purposes.

Next, we annualize estimates of the costs below in Table 36. In this estimate, we take into account the time that different sized farms have to comply with the rule, as well as the different compliance times for agricultural water provisions and for activities relating to sprouts. Estimates are annualized over 10 years. We estimate that the annualized costs of the final rule would be approximately \$368 million per year using a discount rate of 7 percent over 10 years. The average cost per covered farm is \$10,351. We note that within size categories costs borne by individual farms will diverge widely from the averages reported here, depending upon whether or not the farm is already in compliance with most of the provisions of the rule.

Table 36. Summary of Costs for the Produce Safety Rule Considering Time to

Comply with the Rule (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total
Personnel Qualifications and training	\$0.00	\$21.30	\$33.87	\$68.44	\$123.61
Health and Hygiene	\$0.00	\$14.55	\$8.51	\$69.74	\$92.80
Agricultural water	\$0.00	\$6.48	\$1.87	\$7.76	\$16.11
Biological soil amendments of animal origin	\$0.00	\$0.23	\$0.16	\$0.89	\$1.28
Domesticated and wild animals	\$0.00	\$1.22	\$1.28	\$8.50	\$11.01
Growing, harvesting, packing, and holding activities	\$0.00	\$0.48	\$0.22	\$0.73	\$1.42
Equipment, tools, buildings, and sanitation	\$0.00	\$10.09	\$8.71	\$63.33	\$82.14
Sprouting operations	\$0.00	\$0.52	\$0.70	\$4.34	\$5.55
Recordkeeping	\$4.24	\$5.55	\$2.37	\$5.41	\$17.57
Administrative cost to learn the rule	\$1.35	\$5.50	\$2.50	\$5.05	\$14.41
Corrective steps	\$0.00	\$0.38	\$0.27	\$1.54	\$2.19
Variances	\$0.00	\$0.00	\$0.00	\$0.08	\$0.08
Total Costs (annual in millions)	\$5.59	\$66.29	\$60.47	\$235.82	\$368.17
Average Cost per farm*	\$74.65	\$2,910.02	\$15,285.87	\$28,438.88	\$10,350.83

Note: Average costs values not reported in millions.

Annualizing costs over the first ten years after publication of this final rule, costs are expected to be approximately at \$368 million annually at 7 percent and \$389 million at 3 percent.

Table 37. Net Present Value and Annualized Costs of the Produce Safety Rule (in millions)

	Exempt	Very Small	Small	Large	Total
Net present value at 3					
percent	\$37	\$613	\$550	\$2,104	\$3,304
Net present value at 7					
percent	\$28	\$462	\$424	\$1,657	\$2,571
	,				
Annualized at 3 percent					
over 10 years	\$4	\$72	\$65	\$247	\$387
Annualized at 7 percent				1	
over 10 years	\$4	\$66	\$60	\$236	\$366
Average Cost Per Farm at					
3 percent	\$58	\$3,155	\$16,304	\$29,749	\$11,059
Average Cost Per Farm at					
7 percent	\$53	\$2,885	\$15,265	\$28,452	\$10,449

Note: Average costs values not reported in millions.

G. Distributional Effects

We do not expect that the rule will have any adverse distributional effects on any one specific party. That is, depending on how the farms in the affected markets respond to these requirements, some of the costs may ultimately be borne by consumers as price increases. The higher prices, however, will likely not be sufficient to fully offset the costs borne by food establishments. As an overly simple example, if 100 percent of the costs of this rule were passed along directly to consumers this would increase the market price for fresh produce by only 2.1 percent (\$231+ foreign costs + \$560 domestic costs million divided by \$38 billion). Additionally, it is highly unlikely that any one party, either consumers or industry, will bear the entire burden of costs from compliance with this rule. Rather, the costs will likely be shared amongst all parties based on numerous factors such

as the relative price elasticity of the produce market and producers' ability to set prices in the marketplace.

H. International Effects

For the FRIA, we retained the methodology for the number of foreign farms that will be covered by our rule based on the latest number of foreign farms shipping produce to the US. As with domestic farms, we adjust these numbers based on new data sources. Our estimate for the total number of foreign farms exporting produce to the US is approximately 45,000. Of those farms exporting RACs to the US, we estimate that approximately 13,000 might incur compliance costs to continue exporting to the US.¹⁰ Because we lack survey data about baseline foreign farms' food safety practices and the likely costs to incorporate all the changes to comply with the rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic farms; they will have the same proportion of baseline practices and the same proportion of farms not covered or eligible for an exemption. Applying the average annualized cost of the rule for domestic farms of roughly \$10,000 per farm using a 7 percent discount rate (\$11,000 at a 3 percent discount rate) yields an estimated total annualized cost to foreign operations of \$136 million (\$146 million using a 3 percent discount rate). Additionally, those farms that are exempt from or not covered by the rule are estimated to incur the same average costs of domestic exempt or non-covered farms. Applying the average annualized cost of the rule for domestic farms of roughly \$53 per farm using either a 7

¹⁰ This estimate is derived from the total number of entities importing RACs from OASIS data (45,000) multiplied by the percent of domestic farms that are covered by this rulemaking, 29 percent (35,029 covered farms divided by 121,116 total farms). The methodology has not changed from the proposed analysis but both sources of data are now updated.

percent discount rate (\$58 using a 3 percent discount rate) yields an estimated total annualized cost to exempt or non-covered foreign operations of \$1.7 million using a 7 percent discount rate (\$1.8 million using a 3 percent discount rate). Together, we estimate an annual cost to foreign farms shipping produce RACs to the US of \$138 million annualized, using a 7 percent discount rate (\$146 million using 3 percent).

This analysis may overstate or understate the true cost to foreign farms. From our OASIS data, we know that foreign operations will often only send a small fraction of their total production to the US and therefore our estimate is likely the upper bound estimate. If average foreign wage rates are significantly lower than average US wage rates, if total production costs are lower, or if some foreign farms simply cease to ship their products to the US because of the regulatory compliance costs, the total costs to foreign farms might be significantly less. Conversely, if fewer foreign farms are already preforming some of the required activities, or if average foreign wage costs are higher, then the total costs to foreign farms could be higher.

I. Uncertainty and Sensitivity Analysis

1. Costs

A source of uncertainty is our FVAP survey (Ref. 20) The survey is older data, from 1999, and it is highly likely that the produce industry has made significant improvements in safety measures since it was originally conducted. There has been a growing industry wide understanding of the benefits of safe food handling practices and more and more establishments are adopting some food safety controls. If the survey overstates the number of operations that lack our controls today by 25 percent, to account

for trends in industry practices, the total costs of the rule would decline to \$301 million as shown in Table 38.

In addition, it could be that farm food safety practices have actually decreased since this survey was conducted. Therefore we additionally lower the percentage compliance rates by 10% to more fully capture the variability inherent in this analysis. We adjust compliance percentages downwards somewhat less than we adjusted upwards, because we believe that it is much less likely that farms have regressed in their safety activities since the survey was conducted. If the survey understates the number of operations that lack practices compliant with part 112 today by 10 percent, the total costs for the final rule would rise to \$401 million as shown in Table 38.

The costs of the water provisions are another source of uncertainty we address in our sensitivity analysis. We raise water provision compliance rates by 25 percent in our low estimate and decrease them to zero percent in our high estimate. In addition, because the costs to treat water are somewhat more uncertain than some other cost estimates, we also lower water treatment costs to \$32 in our low estimate and raise water treatment costs to \$543 in our high estimate, to capture the full potential range of marginal water treatment costs. Because water costs represent about 6.6 percent of the total costs of the rule, substantial changes such as doubling or halving them would only result in a 6.6 percent increase or a 3.3 percent decrease in the total costs of the rule.

Table 38. Sensitivity Analysis of Costs (in millions)

	Low	High
Annualized at 3 percent	\$319	\$425
Annualized at 7 percent	\$301	\$401

2. Benefits

Previously presented benefits are mean values derived from multiple data ranges and distributions. In order to more fully characterize the expected benefits of this rule and highlight the uncertainty built into this estimation, we present ranges for estimates. Our primary outcomes of interest are presented below in Table 39. For simplicity of interpretation, we only examine the total outcomes, but all estimates previously presented were derived from multiple distributions, including the annual incidence, full costs per pathogen, and efficacy estimates. In our sensitivity analysis below, we run Monte Carlo simulations in which these values vary based on our calculated parameters of their distributions (mean, 5th percentile, 95th percentile). This allows us to calculate low (5th percentile) and high (95th percentile) estimates of the benefits.

Table 39. Sensitivity Analysis of Benefits (in millions)

	Illi	nesses	Benefits (millions)		
	Low	High	Low	High	
Annualized at 3 percent	273,227	449,626	\$748	\$1,195	
Annualized at 7 percent	250,212	412,504	\$710	\$1,132	

Another source of uncertainty in the estimation of benefits is the data on reported outbreaks associated with FDA-regulated produce RACs. The incidence of reported outbreaks varies by year, with some periods of time experiencing more of these outbreaks than others. Because our estimated number of total outbreaks related to FDA regulated produce RACs is calculated as the ratio of reported FDA regulated produce RAC outbreak illnesses to total CDC identified illnesses, the variability in the reported FDA regulated produce RAC outbreak illnesses may lead to an overestimation or underestimation of the total outbreaks related to FDA regulated produce RACs. If the data span used encompasses a time period with a relatively low incidence of reported

FDA regulated produce RAC outbreak illnesses, it may lead to an underestimation of the total outbreaks related to FDA regulated produce RACs, while if it encompasses a time period with a relatively high incidence of reported FDA regulated produce RAC outbreak illnesses, it may lead to an overestimation of the total outbreaks related to FDA regulated produce RACs.

For example, if we examine only the time frame available for the PRIA, 2003-2008, our total estimated benefits would be slightly below \$900 million, as opposed to the \$1.4 billion in steady state benefits we currently estimate; a reduction of approximately 35 percent. Additionally, if we were to exclude the year with the most total reported illnesses attributable to FDA RACs, 2011, our total estimate of benefits would fall by approximately 42 percent, to approximately \$810 million, annually. Conversely, if we were to exclude the year with the least total reported illnesses, 2007, our total estimate of benefits would rise by approximately 8 percent, to approximately \$1.5 billion, annually.

3. Net Benefits

Finally, we compare the range of estimate benefits to the range of estimate costs.

This information is presented in Table .

Table 40. Sensitivity Analysis of Net Benefits (in millions)

	Low	Mean	High
Benefits	\$1,059	\$1,389	\$1,719
Costs	\$301	\$366	\$390
Net Benefits	\$758	\$1,023	\$1,329

J. Analysis of Regulatory Alternatives to the Rule

FDA identified and assessed several regulatory alternatives including: (1) relying

on non-regulatory solutions, (2) a lower or higher monetary value threshold for farms not covered under the rule, (3) longer or shorter compliance periods, and (4) reduced requirements.

1. Non-regulatory Solutions

In the absence of FSMA, under this alternative, FDA could rely on some or all of the following:

- voluntary recommendation of some or all provisions of the regulation,
- current or enhanced State and local enforcement of existing state or local laws to
 bring about a reduction of potential harm from contaminated produce, or
- the tort system, with litigation or the threat of litigation serving to bring about the goals of the rule.

The advantage of this alternative is that it is already in place and the produce industry generally understands the requirements in the rule. The disadvantage of this alternative is that the regime lacks several of the most important provisions of the rule that have the potential to prevent avoidable foodborne illnesses that we estimate are worth approximately \$976 million per year.

By voluntarily introducing procedures, establishments that do so demonstrate that their expected private economic benefits will exceed their private costs. Voluntary adoption of any practices will occur when it is profitable to do so. Although many establishments have adopted some food safety practices in order to meet the public demand for safer produce, numerous surveys show that many farms have not adopted the practices that provide socially optimal levels of food safety.

Public and private health agencies, consumer groups, competitors, trade

organizations or other independent parties could publicize the risks from produce not grown, harvested, packed or held using appropriate practices and allow consumers to decide for themselves about the risks of adulteration. The weakness of this approach is that independent organizations cannot discover food safety hazards until after consumers are sickened. In the absence of the produce safety standards, the burden of monitoring safety practices fall more heavily on consumers.

Finally, FSMA requires that we issue a Produce Safety regulation. Therefore, this is not a legally viable alternative.

2. Lower or Higher Monetary Value Threshold for Farms not Covered

The rule does not cover farms with \$25,000 or less in annual produce sales. As this monetary value threshold falls, the number of farms not covered will fall. Table 41 shows the costs and benefits for a monetary value threshold of \$10,000 in annual produce sales.

Table 41. Lower Monetary Value Threshold for Farms not Covered

	7%	3%
Annualized Costs	\$460	\$489
Annualized Benefits	\$940	\$991

Conversely, as this monetary value threshold rises, the number of farms not covered rises. Table 42 shows the costs and benefits for a monetary value threshold of \$100,000 in annual produce sales.

Table 42. Higher Monetary Value Threshold for Farms Not Covered

	7%	3%
Annualized Costs	\$345	\$364
Annualized Benefits	\$899	\$938

3. Shorter or Longer Compliance Periods

The rule could have established shorter compliance periods, such as one year for farms of all sizes. With a one year compliance period, the affected farms would need to begin the process of compliance immediately. With a one-year compliance period, the costs increase to \$438 million, and smaller farms with fewer resources must adopt the requirements in a time period that does not allow them to adopt the requirements correctly or fully, which might add to their costs and not add to public health. Moreover, FSMA establishes certain minimum compliance periods, so this is not a legally viable option. Table 43 shows the benefits and costs under this option.

Table 43: One-year Compliance Period

	7%	3%
Annualized Costs	\$435	\$450
Annualized Benefits	\$1,089	\$1,125

The rule could have established a longer compliance period for all affected farms, such as three years for large farms and a corresponding extra year for all other farms. With a three -year compliance period, the affected farms would have more time to implement the produce safety standards required by the rule. With a three-year compliance period, the costs decrease to \$308 million as smaller operations with fewer resources are able to implement the requirements in a time period that would allow them to adopt them correctly or fully.

Table 44. One Extra Year Compliance Period (3 years for Large Farms)

	7%	3%	
Annualized Costs	\$307	\$331	
Annualized Benefits	\$771	\$830	

4. Fewer Requirements

Under this Option, the rule could establish less extensive requirements. Several provisions could be combined to provide a less extensive set of standards than those in

the rule. Certain prevention measures could be separated and put forth as stand-alone regulations; for example, requirements regarding agricultural water could be issued as a separate rule. As an alternative, certain provisions could be eliminated altogether; for example, as shown in Table 45, eliminating provisions related to domesticated and wild animals and growing, harvesting, packing, and holding activities would reduce the cost of the rule by nearly \$12 million; however, potential benefits would also be reduced by about \$154 million. Another alternative shown in Table 45 is eliminating provisions related to agricultural water for growing or harvest pathway activities, which would reduce the cost of the rule by nearly \$16 million; however, potential benefits would also be reduced by about \$127 million (annualized at 3 percent).

It is not possible to present each combination of provisions as separate options; however, the individual effects of the various on-farm prevention measures can be seen in the summary of costs and benefits. Dropping measures would, individually, generate lower costs than the integrated program outlined in the rule. However, we also expect that dropping measures would, individually, lead to the number of illnesses prevented being lower than in the integrated program outlined in the text.

Table 45. Fewer Requirements

Eliminating provisions related to do	mesticated and wild animals and holding activities	d growing, harvesting, packing, and	
	7%	3%	
Annualized Costs	\$354	\$374	
Annualized Benefits	\$778	\$822	
Eliminating provisions related	to agricultural water for growing	g or harvest pathway activities	
	7%	3%	
Annualized Costs	\$351	\$371	
Annualized Benefits	\$808	\$849	

5. Summary of Alternatives

Table 46 summarizes the costs and benefits of the rule and under several regulatory alternatives.

Table 46. Summary of Regulatory Alternatives (Present Values, \$ million)

414		Costs	Benefits	Costs	Benefits
Alternative		at 3%	at 3%	at 7%	at 7%
Lower monetary value threshold for farms	Incremental	\$102	\$15	\$94	\$15
not covered	Total	\$489	\$991	\$460	\$940
Higher monetary value threshold for farms	Incremental	-\$23	-\$38	-\$21	-\$26
not covered	Total	\$364	\$938	\$345	\$899
One-year compliance period for all farms	Incremental	\$63	\$149	\$69	\$164
	Total	\$450	\$1,125	\$435	\$1,089
Three-year compliance period for all farms	Incremental	-\$56	-\$146	-\$59	-\$154
	Total	\$331	\$830	\$307	\$771
Fewer requirements: domesticated and wild	Incremental	-\$13	-\$154	-\$12	-\$147
animals	Total	\$374	\$822	\$354	\$778
Fewer requirements: agricultural water	Incremental	-\$16	-\$127	-\$15	-\$117
Tower requirements, agricultural water	Total	\$371	\$849	\$351	\$808
The Rule, as finalized	Incremental				
	Total	\$387	\$976	\$366	\$925

Note: incremental costs and benefits are relative to previously-listed alternative.

III. Final Small Entity Analysis

The Small Business Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Small entities have fewer resources to devote to regulatory compliance and, therefore, may be more affected by regulatory compliance costs. The agency finds that the rule will have a significant economic impact on a substantial number of small entities.

A. Description and Number of Affected Small Entities

The Small Business Administration defines farms involved in crop production as "small" if their total revenue is less than \$750,000 (Ref. 45). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition, and

these farms account for 62 percent of covered produce production. Exempting all of these small entities would substantially reduce the expected health benefit of the rule.

As described in the preamble, section 419(a)(3)(F) of the FD&C Act requires FDA to define the terms "small business" and "very small business." For purposes of this rule, FDA has defined a small business as a farm that is covered by the rule whose average annual monetary value of produce, on a rolling basis, sold during the previous three-year period is no more than \$500,000, and that is not a very small business. FDA has defined a very small business in part 112, as a farm that is covered by the rule and whose average annual monetary value of produce, on a rolling basis, sold during the previous three-year period is no more than \$250,000. See § 112.3(b). The definitions for small business and very small business exclude farms that are not subject to the rule per § 112.4(a), that is, farms with \$25,000 or less in average annual monetary value of produce sold. Approximately 3,956 farms that are covered by the rule are considered small businesses under the rule, and these farms account for 5 percent of covered produce. Approximately 22,781 farms that are covered by the rule are considered very small businesses under the rule, and these farms account for 9 percent of covered produce.

The rule reduces the burden on small entities in part through the use of exemptions: certain small entities are eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (§ 112.5). The rule additionally reduces the burden on small entities by not covering farms with \$25,000 or less of average annual monetary value of produce sold (§ 112.4(a)). The rule additionally provides all farms flexibility for alternative practices to be used for certain specified requirements related to agricultural water, provided the farm has adequate scientific

support (see §§ 112.12 and 112.49). The rule also provides for States, Tribes, and foreign countries to submit a request for a variance for one or more requirements of the rule. To be granted, the procedures, processes, and practices to be followed under the variance must be reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of the rule.

Farms (except sprout operations) defined as small businesses have 3 years to comply with most provisions of the rule after the effective date of the rule, and farms (except sprout operations) defined as very small businesses have 4 years. There is also an additional 2-year compliance period beyond the respective compliance date for certain requirements related to agricultural water. See section XXIV of the rule.

Table 47 summarizes the total number of domestic farms covered by the rule, the percentage of covered farms and produce they account for, and their average annual monetary value of food sold by size. For purposes of the small business analysis, Columns 2 and 3 of the table identify the farms that meet our definition of a very small and small business, respectively.

Table 47. Covered Farms in the Rule

	Very Small	Small	Large	Total
Number of covered farms	22,781	3,956	8,292	35,029
Percentage of covered farms	66%	11%	23%	100%
Percentage of produce acres	9%	5%	60%	74%
Average annual monetary value of food	\$86,000	\$360,000	\$3,450,000	\$882,000

B. Description of the Potential Impacts of the Rule on Small Entities

The costs to implement the rule will vary across farms as their current practices vary, and farms whose practices, processes, or procedures are not already in compliance

with the requirements will bear the costs for compliance. If a farm's profit margin is significantly reduced after the regulatory costs are subtracted from its pre-regulatory revenues, then the farm will be at risk of halting production of the crops that it deems too costly to grow, pack, harvest, and hold. Regulatory cost burdens tend to vary across different-sized farms. Farm size is an important determinant of regulatory impacts and for determining business risk. Small entities with above average costs of doing business will be at a competitive disadvantage. Some small entities might determine that their new expected costs are likely to exceed their revenues.

This may be especially true for small sprouting operations, whose average costs of compliance may be higher due to the additional requirements on their production. We estimate that average revenues for very small sprouting operations are approximately \$49,000 and small sprouting operations are \$67,000. Average costs to very small and small sprouting operations estimated to be approximately \$17,000, or approximately 36 and 26 percent of revenues for very small and small sprouting operations, respectively. These costs are in addition to the other applicable costs of the rule for sprouting operations.

Table 48 shows the average costs and average upfront costs of implementing the requirements of the rule (annualized at 7 percent over 10 years) as a percentage of the average annual monetary value of food sales per very small and small farm. For comparison, we include the results for large farms. Average costs make up 3 percent of the average food sales for very small farms and 4 percent for small farms. Small and very small farms whose practices, processes, or procedures are not already in compliance

with a significant portion of the requirements will incur a larger cost than the average shown.

Table 48. Average Costs of Implementing Proposed Rule as Percentage of Food Sales by Farm Size

	Very Small	Small	Large	All Farms
Average costs of implementing provisions in the proposed rule	\$2,885	\$15,265	\$28,452	\$10,449
Average upfront costs of implementing provisions in the proposed rule	\$5,027	\$23,382	\$36,396	\$14,525.69
Average annual monetary value of food sold	\$86,000	\$360,000	\$3,450,000	\$882,000
Average costs percentage of average annual monetary value of food sold	3%	4%	1%	1%

Note: Because of the timing of the rule, farms will incur upfront costs in different years. Average upfront costs to firms are estimated here by calculating the average cost for farms of different sizes based on the first year in which they incur costs. Additionally, this estimate does not include the costs of the water provisions as these costs are further delayed for farms of all sizes.

C. Alternatives to Minimize the Burden on Small Entities

In the final rule, we have introduced several provisions for regulatory relief for small entities. The most important are the modified requirements for businesses that qualify for a "qualified exemption." In addition, small and very small businesses have additional time to comply with the requirements: small businesses (except sprout operations) have three years and very small businesses (except sprout operations) have four years to come into compliance after the effective date of the final rule. This is an additional 12 months or 24 months, respectively, beyond the time given to larger operations to comply with this rule. We have also provided for extended compliance dates for certain agricultural water requirements for all covered farms with respect to covered produce other than sprouts. See section XXIV of the rule.

The final rule provides substantial cost relief to small businesses. We identified two other options for regulatory relief that were not adopted.

a. Longer compliance period for small businesses

Small entities may find it more difficult to learn about and implement the requirements than it will be for large entities. Lengthening the compliance period for small businesses beyond the additional time we currently allow would provide some additional regulatory relief by allowing small businesses to take advantage of increases in industry knowledge and experience in implementing these regulations. A longer compliance period will allow additional time to learn about the requirements of the rule, to hire or train workers, to take samples for their initial water quality survey, to purchase new or replacement equipment, to arrange financing and for any other initial expenditure of time, effort and money. It will also delay the impact of the annual costs of compliance. The annualized costs savings from the delay are estimated to be approximately \$70 million.

b. Fewer Requirements

The alternative to only require certain provisions and not require others (for example, not require small businesses to comply with the standards related to personnel qualifications and training or those related to agricultural water) would reduce average costs for small businesses. Under this alternative, the costs for all small businesses would be reduced from \$175 million to \$94 million, annualized.

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VALUING REDUCTIONS IN FATAL ILLNESS RISKS: IMPLICATIONS OF RECENT RESEARCH

LISA A. ROBINSONa,* and JAMES K. HAMMITTa,b,c

^aHarvard University (Center for Risk Analysis), Boston, MA, USA ^bToulouse School of Economics (LERNA), Toulouse, France ^cU.S. Department of Health and Human Services, Washington, D.C., USA

ABSTRACT

The value of mortality risk reductions, conventionally expressed as the value per statistical life, is an important determinant of the net benefits of many government policies. US regulators currently rely primarily on studies of fatal injuries, raising questions about whether different values might be appropriate for risks associated with fatal illnesses. Our review suggests that, despite the substantial expansion of the research base in recent years, few US studies of illness-related risks meet criteria for quality, and those that do yield similar values to studies of injury-related risks. Given this result, combining the findings of these few studies with the findings of the more robust literature on injury-related risks appears to provide a reasonable range of estimates for application in regulatory analysis. Our review yields estimates ranging from about \$4.2 million to \$13.7 million with a mid-point of \$9.0 million (2013 dollars). Although the studies we identify differ from those that underlie the values currently used by Federal agencies, the resulting estimates are remarkably similar, suggesting that there is substantial consensus emerging on the values applicable to the general US population. Copyright © 2015 John Wiley & Sons, Ltd.

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KEY WORDS: benefit-cost analysis; value per statistical life; regulation

1. INTRODUCTION

Under Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011), US regulatory agencies are required to assess the costs, benefits, and other impacts of their significant regulations. The value of mortality risk reductions, conventionally expressed as the value per statistical life (VSL), is often a major determinant of the net benefits of these regulations. Thus, the appropriate VSL to be applied in these analyses has received substantial attention.

Guidance for conducting these analyses was issued by the U.S. Office of Management and Budget (OMB) in 2003. While indicating that the then-available research suggested that the VSL was between roughly \$1 million and \$10 million (2001 dollars), OMB allows regulatory agencies to exercise some discretion in selecting the VSL they apply in their analyses.

To date, only two US regulatory agencies have issued formal VSL guidance: the U.S. Environmental Protection Agency (EPA 2000, 2010a) and the U.S. Department of Transportation (DOT 2014). Although there is a 20-year gap between when each first developed its current guidance, the central estimates are remarkably similar. Whether this is coincidence or reflects a consensus in the literature is unclear. More specifically, if updated to 2013 dollars, the central values used by EPA and by DOT are \$9.4 million and \$9.2

^{**}Correspondence to: Harvard University (Center for Risk Analysis), 718 Huntington Avenue, Boston, MA 02115, USA. E-mail: robinson@hsph.harvard.edu

million, respectively. Yet, the EPA value is based on a literature review published in the early 1990s (Viscusi 1992, Viscusi 1993), while the DOT value is based on a review conducted during 2012 and 2013.

Despite differences in the types of mortality risks they regulate, both agencies rely largely on studies that examine the changes in wages associated with changes in occupational risks. DOT regulations typically address the risk of accidental death, similar to the occupational risks included in the wage-risk studies. In contrast, EPA regulations typically address illnesses. However, when EPA first developed its guidance in the early 1990s, few VSL studies of sufficient quality were available that focused on illnesses. The research base has since expanded substantially; EPA has initiated work on updating its values but has not yet announced the results (EPA 2010b, Kling et al. 2011). Thus, the question remains whether the research literature has evolved to the point where high-quality studies are available for mortality risks associated with illness rather than injury.

This question is of particular interest to agencies that primarily regulate illness-related risks, including the U.S. Department of Health and Human Services as well as EPA. We address this issue with a new review that has two goals: (1) to identify studies that meet evolving 'best practice' criteria and (2) to explore the use of such studies to better tailor VSL estimates to the types of risks that are regulated. Meeting the second goal requires greater reliance on stated-preference studies, which use surveys to estimate the VSL for different types of risks and population groups, rather than relying on studies of the preferences revealed by the wage differentials associated with riskier jobs.

Our results are surprising. First, although the number of studies that focus on illness-related risks has increased dramatically, few meet criteria for quality and for suitability for use in US regulatory analysis. Thus, agencies may need to continue to rely at least in part on studies that primarily address injury-related risks.

Second, previous reviews found that stated-preference methods tend to yield substantially smaller VSL estimates than do wage-risk studies (Kochi, Hubbell, and Kramer 2006, Cropper, Hammitt, and Robinson 2011). This contrasts to the findings for other goods, for which stated-preference studies are believed to yield larger values than revealed-preference studies, perhaps because survey respondents pay insufficient attention to their budget constraints and overstate their willingness to pay (WTP) when choices are hypothetical.³ However, we find that the few stated-preference studies that meet more stringent selection criteria yield estimates close to the wage-risk estimates, suggesting that the differences previously found may result, at least in part, from issues related to study design.

While our results imply that the literature on illness-related risks is not yet robust enough to be used as the sole basis for the VSL estimates applied by regulatory agencies, they also suggest that the values for illness-related risks may be within the same range as the values for injury-related risks. Thus, population-average values in the same range as those currently used by EPA and DOT may continue to be appropriate for application across these and other agencies. In the sections that follow, we first introduce the conceptual framework for valuing mortality risk reductions, then discuss the conduct of our review, and finally summarize the results and implications.

2. CONCEPTUAL FRAMEWORK

The starting point for valuation is a risk estimate that quantifies the impact of each regulatory option on each health endpoint of concern, often expressed in terms of the average individual change in the probability of death within a particular time period. The calculation is straightforward: the average individual risk reduction (e.g., 2/10,000) is multiplied by the number of individuals affected (e.g., 200,000 annually) to estimate the number of statistical cases averted (40 given the previous values). For major regulations, these risk changes are usually

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¹Values from EPA (2010a, Appendix B) adjusted by the authors following EPA's approach, using the gross domestic product deflator and income adjustment factors from EPA (2015). Each agency also provides values to be used to assess uncertainty. EPA (2015, Appendix I) suggests applying a Weibull distribution (with scale = 5.32E-6 and shape = 1.509588), and DOT suggests a low of \$5.2 million and a high of \$13 million (2013 dollars and income levels).

²The EPA VSL is derived from 26 studies, 21 of which are wage-risk studies; the remaining five are surveys that address job-related or motor vehicle-related risks. The DOT VSL is derived from nine wage-risk studies.

³Whether stated-preference studies systematically lead to overestimates has been debated in the environmental economics literature; some commenters are skeptical about the validity and reliability of the responses more generally. See, for example, Carson (2012), Hausmann (2012), and Kling, Phaneuf, and Zhao (2012).

small at the individual level but may account for a large number of cases once aggregated over the affected population. Generally, we cannot predict in advance who will survive for a longer period if the regulation is implemented. The risk reduction is a 'statistical' case—a sum of probabilities. Thus, 'saving' a statistical life is not the same as preventing an identifiable individual from dying within a particular time period.

Under conventional economic assumptions, individual WTP is the appropriate measure of the value of these risk reductions, given that they are improvements from the status quo. Thus, valuation requires estimating the maximum an individual would be willing to pay for the risk change he (or she) would experience, given his preferences and budget constraint (i.e., his compensating variation). These values reflect the rate of trade-off between money and mortality risk and are conventionally reported in units of dollars per statistical life saved within a defined period; e.g., \$900 WTP÷1/10,000 annual risk change=\$9.0 million VSL.

An alternative, older measure of the value of reducing mortality risk is the cost of illness or human capital approach. This approach values a change in mortality risk by the expected change in productivity losses and may also include medical expenses. VSL is expected to be larger than expected productivity loss, because it includes the utility gains from living in addition to productivity and market consumption. In contrast, the cost of illness approach often includes medical costs paid by third parties, which are typically not included in VSL. The social value of reducing mortality risk should include both the private value (measured by VSL) and any net saving in medical or other costs incurred by third parties (see Robinson and Hammitt, 2013, for more discussion).⁴

Individual WTP for mortality risk reductions will vary between individuals and may depend on the characteristics of the risk. For example, WTP may depend on when the risk reduction occurs relative to the change in exposure (latency or cessation lag); on individual characteristics such as age, health status, and remaining life expectancy; and on risk characteristics such as whether it involves a fatal traumatic accident (e.g., a motor vehicle or airplane crash), an acute health event (e.g., heart attack or stroke), or a chronic degenerative disease (e.g., cancer or lung disease).

These values are often estimated using revealed-preference studies, which have the advantage of relying on behavior with real consequences. However, it is difficult to find market choices that can be used to estimate how the VSL varies depending on certain risk and population characteristics, including the risk of death from illness rather than injury. Stated-preference methods are necessary in these cases, typically employing survey techniques to ask respondents about their choices in a hypothetical setting. Researchers can tailor these surveys to directly value the outcome of concern. For example, the survey can describe a particular type of illness from a particular type of exposure. A weakness is that respondents do not face significant consequences from their choices and therefore may have limited incentives to consider the questions carefully. As a result, such surveys must be carefully designed and administered, and satisfy various tests for coherence, to be considered reliable for use in regulatory analysis.

Because of time and resource constraints, regulatory analysts generally rely on existing valuation studies rather than conducting new research that considers the risks addressed by a particular regulation (Robinson and Hammitt 2013). This approach, referred to as 'benefit transfer', requires reviewing the literature to identify high-quality studies that are suitable for use in the particular context. Quality can be evaluated by considering the likely accuracy and reliability of the data and methods used, referencing guidance on best practices. Suitability or applicability involves considering the similarity of the risks and the populations affected. Qualitative and, if possible, quantitative assessment of uncertainty is always needed to characterize the limitations of the available research and the implications for decision-making.

3. SELECTION CRITERIA

The VSL is relatively well studied, and substantial attention has been paid to developing criteria for evaluating study quality and applicability consistent with the benefit transfer framework. Well over 100 VSL studies have

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⁴For mortality, the cost of illness tends to be dominated by productivity losses. Grosse et al. (2009) found that the present value of future lifetime production for a 40 to 44 year old is \$1.2 million if both market and nonmarket production are included and \$0.8 million if only market production is included (2007 dollars, 3% discount rate). These values are much smaller than the VSL estimates discussed later in this article.

Table I. Selection criteria

General criteria

- 1. Be publicly available.
- 2. Be written in English.
- 3. Provide estimates for the general US population.

Criteria for revealed-preference studies

- 4. Use hedonic methods that address the trade-off between wages and job-related risks.
- 5. Control for potentially confounding factors, such as nonfatal injury risk as well as both industry and occupation.
- 6. Rely on high-quality risk data, equal or superior to the Census of Fatal and Occupational Injuries.

Criteria for stated-preference studies

- 7. Elicit values for private risk reductions that accrue to the respondent.
- 8. Express the risk change as a probability (not as a life extension).
- 9. Estimate willingness to pay, not willingness to accept compensation.
- 10. Provide evidence of validity, including sensitivity of willingness to pay to changes in risk magnitude.

been published in the peer-reviewed literature.⁵ Until recently, this literature was dominated by revealed-preference studies that address occupational risks. This is no longer true, as the number of stated-preference studies has increased substantially, addressing environmental, traffic safety, and other risks.

This progress has been accompanied by an evolving understanding of best practices. Thus, the starting point for our review is recent work that focuses on establishing criteria for the values used in US regulatory analysis, particularly EPA's white paper on valuing mortality risk reductions (EPA 2010b), its Science Advisory Board's review of that paper (Kling et al. 2011), DOT's VSL guidance (DOT 2014), and a review article (Cropper, Hammitt, and Robinson 2011) that addresses methodological advances. We also consider the best practices discussed in OMB's 2003 guidance while recognizing that it does not reflect more recent developments. The resulting criteria are divided into three categories, as listed in Table I.

The general criteria relate to the overall context for applying these values. Regulatory analyses are intended to inform decision-makers and the public about the impacts of the policy options considered. Thus, it is important that those reviewing the analysis be able to access the data sources used, including the studies that underlie the VSL estimates. Because we are interested in studies for use by US regulatory agencies, we restrict our search to studies that reflect the preferences of the US population.

Although revealed-preference studies usually address risks associated with injuries rather than illnesses, we include them in our review for comparison to the stated-preference research. The criteria that apply to revealed-preference studies limit the scope to wage-risk studies. Some revealed-preference studies instead evaluate averting behaviors, i.e., defensive measures or consumer products used to protect against perceived health risks. These studies are applied infrequently in regulatory analysis because of concerns about their limitations, including the difficulty of estimating the size of the associated risk change and the need to separately estimate the value of key inputs such as the time spent in the activity.

We include only those wage-risk studies that control for potentially important confounding factors such as nonfatal injury risks and both occupation and industry. We also consider only those that rely on risk data at least as good as the Census of Fatal Occupational Injuries (CFOI). The CFOI was implemented in 1992 by the Bureau of Labor Statistics and is based on review of a comprehensive set of records supplemented by additional confirmation of the data.

The criteria that apply to stated-preference studies focus on those that provide estimates of individual WTP for reductions in the respondent's own risks, consistent with the concept of consumer sovereignty. Some studies instead address risk reductions to the community at-large; these do not appear to estimate individuals' tradeoffs between own wealth and risk. For example, some find (counterintuitively) that WTP for a private risk reduction is higher than WTP for a public program that also affects others (see, e.g., Svensson and Johansson 2010, Lindhjem et al. 2011). This result suggests that respondents may not fully accept the scenario presented in the survey; for instance, they may not believe that the public program will be effective. Another complication is

⁵For reviews, see Viscusi and Aldy (2003), EPA (2010b), Lindhjem et al. (2011), and Viscusi (2014).

concern about the role of altruism in benefit—cost analysis, because a pure altruist would care about how those affected value the costs imposed on them as well as the benefits they receive (Jones-Lee 1991, Bergstrom 2006).

We also limit our selection of stated-preference studies to those that express the risk change as a probability rather than as life extension. We are aware of only one US study (Morris and Hammitt 2001) that elicits values for life extension. While it suggests that the life extension approach is promising, more work is needed. For example, respondents may not understand that the risk reduction affects each year of life; it is not simply added to the end of one's lifespan when one's quality of life is likely to have declined.

To be selected, stated-preference studies must elicit WTP rather than willingness to accept compensation (WTA).⁶ Because regulations typically involve expenditures for improvements from the status quo rather than compensation for damages, WTP is conceptually the more appropriate measure. WTP is also more frequently studied, and the estimates are considered more reliable; the large and variable differences between estimated WTP and WTA are poorly understood (Horowitz and McConnell 2002, Tuncel and Hammitt 2014).⁷

Finally, we require that stated-preference studies provide evidence of validity. A major concern is that respondents may not report their true WTP because the payment is hypothetical. In addition, research suggests that survey respondents often do not understand small probabilities. Thus, we focus in particular on scope tests that indicate whether estimated WTP is sensitive to the magnitude of the risk reduction. Economic theory suggests that WTP should increase almost proportionately to the size of the risk change, as long as the change is small, which means that the VSL should be independent of the risk reduction that is valued (see Hammitt and Graham 1999, Corso, Hammitt, and Graham 2001). For larger risk changes, WTP will be increasingly limited by income, reducing the VSL.

The selection criteria do not explicitly address the date when the studies were completed. However, they do so implicitly. The first wage-risk study that relied on CFOI data was published in 2003 (Viscusi 2013); thus, Criterion 6 (data at least equal in quality to the CFOI) effectively limits our selection of revealed-preference studies to those published in 2003 or later. The starting point is not as clearly defined for the stated-preference studies. However, we exclude studies published in 1993 or earlier for several reasons. First, they were conducted before the issuance of an expert panel report (National Oceanic and Atmospheric Administration 1993) that significantly influenced the conduct of stated-preference studies. Studies conducted after that time are more likely to meet Criterion 10, related to evidence of validity. Second, most of the older studies use small, specialized samples that are not representative of the overall US population. Third, preferences elicited over 20 years ago may not accurately reflect preferences at the present time.

To identify studies that meet the selection criteria, we started with those listed in recent reviews. To supplement and update these lists, we searched the EconLit bibliographic database for subsequently published articles. We also contacted VSL researchers to locate working papers and forthcoming articles, and used the citations in each paper to identify additional studies.

4. RESULTS

In this section, we describe the results of our review of the revealed-preference and stated-preference studies that provide population-average values, including studies that address deaths due to injury as well as illness for comparison. We discuss adjustments for health status and age in the following section.

effect and loss aversion may lead to substantial differences.

⁹For this result, 'small' means that WTP is small relative to the individual's budget constraint.

⁶This criterion primarily affects the selection of stated-preference studies because revealed-preference studies typically address a market equilibrium rather than a change that can be characterized as WTP or WTA. However, recent work (Kniesner, Viscusi, and Ziliak 2014) suggests that there is not a significant divergence between revealed preference estimates of WTP and WTA for job-related risks.

⁷While standard economic theory suggests that WTP and WTA will be similar in many cases, prospect theory suggests that the endowment

⁸There are two types of tests for sensitivity to risk magnitude. External scope tests compare WTP between subsamples of respondents presented with different risk changes, while internal scope tests compare WTP for different risk changes from the same respondents. External tests are preferred because internal tests can be influenced by a respondent's effort to provide internally consistent responses.

Table II. Selected US wage-risk studies (2013 dollars)

Study	Highlighted VSL estimates ^a
Viscusi (2004) Kniesner and Viscusi (2005) Hersch and Viscusi (2010) Lee and Taylor (2013) Scotton (2013) Viscusi (2013)	\$6.8 million ^b \$6.8 million ^b \$8.6 million ^b \$2.1 million to \$4.1 million \$9.2 million to \$20.8 million \$8.6 million to \$12.0 million

Note: VSL, value per statistical life.

4.1. Revealed-preference studies

For the US hedonic wage studies, we first reviewed individual studies and then considered a subsequently completed meta-analysis that follows an approach that appears consistent with our selection criteria. We started with the studies DOT identified in developing its VSL recommendations (DOT 2014) and supplemented that list with studies identified in a subsequent review by Viscusi (2013) as well as those identified through our literature search and contacts with researchers.

These sources yield a total of 16 US wage-risk studies published between 2003 and 2014, of which the six listed in Table II met our selection criteria. ¹¹ The highlighted VSLs range from \$2.1 million to \$20.8 million, with most between \$6.8 million and \$12.0 million. The lowest values (\$2.1 million to \$4.1 million) are from a working paper that experiments with the use of Occupational Safety and Health Administration inspection data (Lee and Taylor 2013), while the highest (\$9.2 million to \$20.8 million) are from a paper where the author notes, '[t]he intent of this study is not to posit a particular value for the VSL; rather, it is to demonstrate how the construction of the fatal risk rate measure impacts the magnitude of the VSL estimate' (Scotton 2013, p. 65).

Of the studies we reviewed, two (Viscusi 2004 and Kniesner, Viscusi, Woock, and Ziliak 2012) focus explicitly on developing national estimates for application in US policy analysis, while others experiment with different approaches and explore sources of variation in the estimates. When inflated to 2013 dollars, the estimates highlighted by the authors of these two studies are about \$6.8 million and \$5.3 million to \$13.2 million, respectively, very similar to the range indicated in Table II, particularly if the relatively high and low values highlighted by Lee and Taylor and by Scotton are excluded.

Recently, Viscusi (2015) completed a meta-analysis that appears consistent with our selection criteria and that directly addresses the goals of this review. The analysis includes 17 studies that rely on CFOI data and controls for whether they address potentially confounding variables such as workers' compensation and nonfatal injury as well as other study characteristics.¹³ Rather than selecting a single estimate from each study, Viscusi

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Health Econ. 25: 1039-1052 (2016)

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^aEstimates are those highlighted by authors in article abstract or conclusions unless otherwise noted, inflated using the Consumer Price Index (http://www.bls.gov/data/inflation_calculator.htm). Not adjusted for real income growth.

bVSL estimates based on those reported in DOT (2014), Table I.

¹⁰Previous meta-analyses of the wage-risk literature have been criticized in part for not applying carefully developed, explicit criteria for selecting studies for inclusion (EPA 2006, Cropper et al. 2007).

selecting studies for inclusion (EPA 2006, Cropper et al. 2007).

The 10 excluded studies are Jennings and Kinderman (2003), Evans and Smith (2008), Viscusi and Hersch (2008), Evans and Schaur (2010), Kniesner, Viscusi, and Ziliak (2010), Scotton and Taylor (2011), Lavetti (2012), Kniesner, Viscusi, Woock, and Ziliak (2012), DeLeire, Khan, and Timmins (2013), and Kniesner, Viscusi, and Ziliak (2014). We generally exclude these studies because they address only a subset of workers and/or do not control for occupation as well as industry; one (DeLeire et al.) does not report a full sample VSL. Determining whether to exclude the three Kniesner et al. studies is difficult, however. They have the advantage of relying on panel rather than cross-sectional data, but exclude women. (The extent to which results are dissimilar for men and women varies across studies and in part reflects the changing roles of women in the workplace.) However, their results are generally within the same range as the included studies.

¹²As noted earlier, the Kniesner et al. study is not included in Table II because it addresses only men but has the advantage of relying on longitudinal data.

¹³The 17 studies include Aldy and Viscusi (2008), Evans and Schaur (2010), Hersch and Viscusi (2010), Kniesner and Viscusi (2005), Kniesner et al. (2012), Kniesner, Viscusi, and Ziliak (2006, 2010, 2014), Kochi and Taylor (2011), Scotton (2013), Scotton and Taylor (2011), Viscusi (2003, 2004, 2013), Viscusi and Aldy (2007), Viscusi and Hersch (2008), and Viscusi and Philip (2014). Some of these studies do not meet all of our selection criteria, but the controls that Viscusi (2015) included for study characteristics address many of the concerns that led to their exclusion.

includes all of the estimates each reports. In addition, he addresses the potential effects of reporting (publication) bias that may occur when a researcher reports only a subset of his or her findings, or when journals are unwilling to publish findings that depart significantly from previous results or appear inconsistent with theory. Depending on the model specification, his bias-corrected results range from \$7.6 million to \$13.7 million (2013 dollars), very similar to the range found in our initial review of individual studies.

Thus, our review results in three overlapping ranges of estimates for US workers. First, as indicated in Table II, our review of individual studies suggests that the VSL likely to be in the range of \$6.8 million to \$12.0 million. Second, if we consider only the two studies that are focused more explicitly on developing national estimates, the range becomes \$5.3 million to \$13.2 million. Third, the recent Viscusi meta-analysis provides a range from \$7.6 million to \$13.7 million. The mid-points of the three ranges are \$9.4 million, \$9.3 million, and \$10.7 million, respectively, only slightly above the central values now used by EPA and DOT.

4.2. Stated-preference studies

The studies discussed earlier do not address illness-related risks; we also reviewed the stated-preference literature to develop a better understanding of how the values might vary. We focus on individual studies because the available meta-analyses of stated-preference research (e.g., Kochi et al. 2006, Dekker et al. 2011, Lindhjem et al. 2011) are not limited to studies that meet our selection criteria.

Our starting point is the US studies included in EPA's review (EPA 2010b; Table III) as supplemented by Kling et al. (2011). We added studies from a comprehensive database developed by the Organisation for Economic Co-Operation and Development (OECD) as well as those identified through our literature search and contacts with researchers. The result was more than 40 articles, although in some cases an individual survey was discussed in multiple articles. However, several of these studies were published prior to 1993, raising concerns about their quality and applicability as discussed earlier.

We first screened the studies to select those that satisfy our selection criteria, finding seven articles published subsequent to 1993 that are based on a national US sample and elicit WTP for the respondent's own risk reduction. We then reviewed the evidence of validity provided in these seven studies in more detail. Of these, three (listed in Table III) meet our selection criteria and demonstrate stronger evidence of validity, including sensitivity to risk magnitude. Corso, Hammitt, and Graham (2001) and Hammitt and Haninger (2010) found that WTP is close-to-proportional to changes in risk magnitude. Cameron and DeShazo (2013) relied on a complex valuation survey that includes illnesses of varying severities and durations, requiring specialized modeling techniques that make it difficult to determine whether WTP is proportional to the risk change. However, in a detailed handbook that supplements their journal articles (Cameron and DeShazo 2012), they provide evidence that respondents understand the scenarios and are sensitive to changes in risk magnitude.

In contrast, the remaining four studies, excluded from Table III, report results that are largely insensitive to the risk change (Hammitt and Graham 1999), are much less than proportionate (Alberini et al. 2004, Chestnut et al. 2012), or do not describe the degree of proportionality (Viscusi et al. 2014). In the first two cases, the size of the VSL that results is very sensitive to the size of the risk reduction presented in the survey, and the lack of proportionality suggests that respondents may not have fully understood what they were being asked to value. In the third case, it is unclear whether the study meets our criterion for validity. ¹⁶

¹⁴The DOT (2014) guidance includes only wage-risk studies.

¹⁵ The OECD database is available at www.oecd.org/env/policies/vsl. We thank David Metz of Industrial Economics, Incorporated for his assistance in identifying these studies.

¹⁶In 2013 dollars, the VSL estimate highlighted by Viscusi et al. (2014) is \$11.1 million, at the high end of the range provided by the included studies. The results from the other excluded studies are as follows: Hammitt and Graham (1999), \$1.2 million to \$68.3 million; Alberini, Cropper, Krupnick, and Simon (2004) (with additional results reported in Alberini, Cropper, Krupnick, and Simon 2006), \$1.0 million to \$6.5 million; and Chestnut, Rowe, and Breffle (2012), \$5.2 million to \$6.5 million.

Table III. Selected US stated-preference studies (2013 dollars)

Study	Highlighted VSL estimates ^a
Corso, Hammitt, and Graham (2001) ^b Hammitt and Haninger (2010) Cameron and DeShazo (2013) (sudden death scenario) ^c	\$4.2 million to \$5.9 million \$6.7 million to \$11.2 million \$8.5 million

Note: VSL, value per statistical life.

Only two of the three studies with greater evidence of validity address illness-related risks. Hammitt and Haninger (2010) estimated VSL for various fatal illnesses (cancer and noncancer) from ingesting pesticide residues on food as well as for motor vehicle accidents, and Cameron and DeShazo (2013) considered several types of hazards and illness profiles. In contrast, Corso, Hammitt, and Graham (2001) considered only motor vehicle accidents.

In sum, although a large number of stated-preference studies have been completed in recent years, very few meet our selection criteria. This suggests that continued work is needed to improve the quality of these studies and to provide valid results, as well as to provide more information on the value of illness-related risks. However, those few studies that meet the criteria yield VSLs ranging from \$4.2 million to \$11.2 million, very similar to the range resulting from our review of the wage-risk studies.

5. ADJUSTMENTS FOR HEALTH STATUS AND AGE

The review in the above sections focuses on VSL estimates for the general population. However, some regulations address illnesses that disproportionately affect those whose health is impaired or who are very young or very old. In this section, we briefly review the related literature, including studies that do not meet the selection criteria discussed earlier.

5.1. Health status

The wage-risk studies discussed earlier include only those who are healthy enough to work by definition, while the stated-preference studies include a sample of the general population. In contrast, some regulations primarily affect the risk of illness among those who are in better or (more often) worse health than the typical US citizen. In addition, because health-related quality of life declines with age (e.g., Hanmer et al. 2006, Fryback 2007), regulations that primarily provide mortality risk reductions to older individuals will largely benefit those who tend to be in worse than average health.

Dockins, Maguire, and Simon (2006) reviewed the evidence on the effects of health status on the VSL and noted that theory is ambiguous. In simple terms, this ambiguity results from the trade-off between spending to increase the likelihood of survival and conserving wealth for expenditure on other goods or services. The effects are potentially counterbalancing: an individual may value risk reduction more if he or she is in good health, but good health may also provide more opportunities for other expenditures, increasing the marginal utility of spending.¹⁷

^aEstimates highlighted by authors in abstract or conclusions or reported range if none highlighted. Inflated using the Consumer Price Index (http://www.bls.gov/data/inflation_calculator.htm); not adjusted for real income growth.

^bResults for logarithmic scale and dot array visual aids.

^cStudy addresses a wide range of illness profiles.

¹⁷See Hammitt (2000) and Hammitt (2002) for more detailed discussion of the theoretical issues and related empirical research. Viscusi and Evans (1990), Sloan et al. (1998), and Finkelstein et al. (2013) explored the effects of health status on the utility of income; their findings suggest that the marginal utility of income is smaller when health is impaired.

The limited empirical research on the effect of health impairments on the VSL is inconclusive, with mixed results. The results vary depending on factors such as the nature and the severity of the health condition as well as the individual's age (e.g., Alberini et al. 2004, DeShazo and Cameron 2005, Evans and Smith 2008). Disentangling the effect of health status from the effects of these other characteristics is very difficult. Thus, whether and how to adjust a population-average VSL to reflect differences in health status is highly uncertain.

5.2. Age

The studies we discuss earlier provide values for adults; some also include older teens. All of the wage-risk studies exclude individuals above the typical retirement age (e.g., over age 62 or 65 years), while the stated-preference studies include older individuals. Thus, on average, the values we report are for those in middle age rather than for the much younger or much older individuals who are disproportionately affected by some illnesses targeted by regulation.

Because older individuals have fewer expected life years remaining than the average member of the population, intuition suggests that lower VSL estimates may be applicable. However, both theory (Hammitt 2007) and empirical work suggest that relationship is uncertain. Some argue that the relationship between VSL and age should follow the pattern of consumption over the lifecycle, which is typically an inverse-U distribution. Much of the empirical work that considers the trade-off between wages and risks across all workers supports this model (Aldy and Viscusi 2007, Viscusi and Aldy 2007, Aldy and Viscusi 2008), although the rate of increase and decrease and the age at which VSL peaks vary across studies. In contrast, a series of wage-risk studies focused on older workers (age 51 years and above and their spouses) finds that the VSL remains constant or increases with age (summarized in Evans and Smith 2006).

Stated-preference research is needed to address the relationships between age and VSL among individuals older or younger than working age. For older individuals, the stated-preference evidence is inconsistent. Some studies do not find statistically significant relationships with age, while others find that the VSL decreases among older individuals in varying patterns and amounts (Krupnick 2007). One more-recent study (Cameron, DeShazo, and Stiffler 2010) finds an inverse 'U' relationship, similar to many of the wage-risk studies. Thus, there is substantial uncertainty regarding the relationship between the population-average VSL and the VSL most appropriate for older individuals.

Because children generally lack the independent financial means as well as the cognitive ability needed to respond to WTP questions, related research generally elicits parental WTP (see Dockins et al. 2002, and EPA 2003, for more discussion). Several studies, conducted in the USA and elsewhere and using varying methods, suggest that WTP for reduced morbidity or mortality risks to children may be noticeably greater (perhaps by a factor of two) than adult WTP to reduce their own risks, although the magnitude of the difference varies across studies. ¹⁸ Thus, while it may be appropriate to apply a higher VSL to children than to adults, the amount of increase and the extent to which it varies for children of different ages are uncertain.

At times, a value per statistical life year (VSLY) estimate is used to adjust for age. In contrast to the VSL, which is the rate at which the individual substitutes money for reductions in current mortality risk (within the current year or other short time period), the VSLY is the rate at which he or she substitutes money for gains in life expectancy (or in discounted life expectancy; see Hammitt 2007, for more discussion). VSLY is often estimated by dividing VSL by the average (discounted) remaining life expectancy for the population studied. To determine the value per statistical case, the constant that results is then multiplied by the expected years of life extension for individuals affected by the policy. Under this approach,

Health Econ. 25: 1039-1052 (2016)

¹⁸Examples include Liu et al. (2000), Dickie and Messman (2004), Dickie and Gerking (2007), Agee and Crocker (2007), Agee and Crocker (2008), Hammitt and Haninger (2010), and Blomquist, Dickie, and O'Conor (2011). One study (Alberini et al. 2010) finds more ambiguous results.

the per-case values are lower for older individuals than for younger individuals, because they have fewer years of expected life remaining.

This approach assumes that VSLY is constant and independent of the number of life years gained, implying that VSL is proportional to the individual's remaining (discounted) life expectancy. However, neither economic theory (Hammitt 2013) nor available empirical results support these assumptions, suggesting (as discussed earlier) that the relationship between the VSL and age is very uncertain. Thus, while applying a population-average VSL appears reasonable when a regulation affects the general population, it is unclear how it should be adjusted in cases where the very young or the very old are disproportionately affected.

6. SUMMARY AND CONCLUSIONS

This review of the literature identifies several high-quality studies that meet our selection criteria. Most are wage-differential studies that address injury-related risks among adult workers and hence do not provide direct information about how to value mortality risk reductions associated with illness. The few studies that both meet our criteria and address illness-related risks provide similar values. More work is needed to explore the extent to which these values are likely to vary depending on the population affected and the characteristics of the health condition.

Our initial review of individual wage-risk studies suggests that the VSL ranges from roughly \$5.3 million to \$13.7 million (2013 dollars) with a mid-point of \$9.5 million. The estimates from the three stated-preference studies that satisfy our criteria yield a slightly lower range, from \$4.2 million to \$11.2 million with a mid-point of \$7.7 million. In combination, this results in a range from \$4.2 million to \$13.7 million with a mid-point of \$9.0 million (2013 dollars). Thus, regardless of which subset of the selected studies we include, a central estimate of population-average VSL around \$8 million or \$9 million appears reasonable.

The available values for illness-related risks appear very similar to those for injuries. The range from the two stated-preference studies that include illness-related risks is \$6.7 million to \$11.2 million with a mid-point of \$8.6 million, within the overall range that results from the larger group of studies

These estimates reflect adjustment of the values reported in the original studies only for inflation. The data in the oldest of these studies were collected in 1997, and real income has increased somewhat over the intervening years. The sensitivity of the VSL to changes in real income is uncertain, but an income elasticity of 1.0 appears to provide a reasonable central estimate given the available evidence. Because real income has been growing slowly, and declining in some recent years, applying this elasticity and adjusting for real income growth to 2013 leaves the range unchanged.

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¹⁹Because of this uncertainty, two expert panels (Cropper et al. 2007, National Academies 2008) recommend against the use of a constant VSLY, suggesting that more research is needed.

²⁰Federal agencies generally do not use different VSL estimates for individuals with different incomes, because doing so raises concerns about the equitable treatment of richer and poorer segments of the population in policy analysis. However, they do adjust the VSL for population-average changes in real income over time, using the same income-adjusted VSL for all members of the population affected by the rulemaking. EPA (2010a) typically uses a distribution of income elasticity estimates with a mode of 0.40 and endpoints at 0.08 and 1.00; DOT (2014) applies an income elasticity of 1.0.

²¹In older research, contingent valuation studies and wage-risk meta-analyses tended to yield elasticities below 1.0, while longitudinal studies and cross-country comparisons yielded elasticities well in excess of 1.0 (Hammitt and Robinson 2011). Recent studies tend to support higher elasticities. For example, Kniesner, Viscusi and Ziliak (2010) found that elasticity generally declines as income rises in the USA, decreasing from 2.24 in the lowest quantile to 1.23 in the highest quantile, with a mean of 1.44. In the Viscusi (2015) meta-analysis of US wage-risk studies discussed earlier, income elasticity ranges from about 0.76 to 1.14 depending on the model specification. Elasticities greater than 1.0 mean that individuals' WTP for small mortality risk reductions becomes a smaller percentage of income as income falls, which appears consistent with the constraints faced by those with lower incomes. Thus, while elasticities above 1.0 appear sensible, the value is uncertain given the diverse results of the available studies.

²²For this adjustment, we use Current Population Survey data on income growth that reflects annual averages for median usual weekly earnings of full-time wage and salary workers.

These studies provide population-average values. Our review of the literature on the effects of health status and age on the VSL is inconclusive for several reasons. First, the available studies lead to inconsistent conclusions about the magnitude of the adjustment and its direction. Second, many of these studies do not meet our selection criteria. Finally, applying any adjustment to the values resulting from our review requires accounting for differences in the baseline used in the comparisons. For example, it is unclear how to apply an age adjustment that compares values for individuals over age 50 years to base values that result from studies that largely address 18 to 65 year olds. More work is needed to determine whether and how to adjust the range of estimates for variation in age and other characteristics.

In sum, given the current state of the valuation literature, it seems reasonable to apply a VSL estimate of \$9.0 million in US regulatory analyses and to test the sensitivity of the results to values ranging from \$4.2 million to \$13.7 million. The available research is insufficient to estimate the extent to which the VSL is likely to vary depending on the characteristics of the risk and the affected population. However, the few high-quality studies of illness-related risks available suggest that these values may be similar to the values for injury-related risks.

The values applied to mortality risk reductions, and the results of the benefit—cost analysis more generally, are only a few of the many factors considered in regulatory decisions. Statutory requirements, implementation issues, and the distribution of the effects are also of interest to decision-makers and the general public. However, the analysis provides important insights into the extent to which those affected are likely to value the risk reductions they receive more or less than the costs imposed by the regulations.

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Policy Monitor

How US Government Agencies Value Mortality Risk Reductions

Lisa A. Robinson*

Introduction

Each year, US government agencies promulgate health and safety regulations that impose hundreds of millions of dollars of costs on the national economy. A key issue in developing these regulations is determining whether the value of the associated risk reductions and other benefits exceeds the value of the resources diverted from other purposes. This article explores one component of this benefit-cost comparison: the approaches used by federal agencies to estimate the value of changes in the risk of premature mortality.

After introducing key concepts, the article describes current federal agency practices. It first summarizes US government-wide guidelines for valuing mortality risk reductions and then discusses the practices of individual agencies in more detail. It focuses largely on the approaches used by the US Environmental Protection Agency (EPA). The EPA is responsible for a substantial proportion of all federal life-saving regulations, and mortality risk reductions account for the majority of the monetized benefits for most of its economically significant rules.

Key Concepts

Most major life-saving regulations reduce mortality risks across a wide population and result in a small change in risk for many affected individuals. Economists have developed the concept of a "statistical life" as a method for aggregating these small changes. For example, a regulation that reduces risks by one in one hundred thousand on average throughout a population of a hundred thousand individuals can be described as saving one statistical

*Harvard Center for Risk Analysis, Harvard University; E-mail: Robinson@hsph.harvard.edu and Lisa.A.Robinson@comcast.net

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284 L. A. Robinson

life—as can an effort that achieves an average risk reduction of one in ten thousand throughout a population of ten thousand. Thus a statistical life is an analytic construct; its value is not equivalent to the value of saving the life of a particular individual.

The Value of Statistical Life

In regulatory analysis, the value of reduced mortality risks usually takes the form of a "value per statistical life" (VSL). If, for instance, each member of a population of a hundred thousand was willing to pay \$50 on average for a one in one hundred thousand decrease in his risk of dying during the next year, the corresponding VSL would be \$50 × 100,000 or \$5 million. Generally, economists estimate these values using either revealed or stated preference studies. Revealed preference methods use data from market transactions or observed behavior to estimate the value of nonmarketed goods. For example, in compensating wage differential (or wage-risk) studies, researchers compare earnings across different industries to estimate the additional wages paid to workers in riskier jobs, using statistical methods to control for the effects of other factors (such as education) on earnings. Stated preference methods use contingent valuation surveys or similar approaches that ask respondents to report their willingness to pay (WTP) for reduced risks under hypothetical scenarios. The VSL is most often estimated from studies of compensating wage differentials; however, a smaller number of studies estimate the VSL using contingent valuation surveys.

Agencies face three challenges in valuing mortality risks: they must select appropriate studies from the available literature, they must adapt the study estimates to the regulatory context, and they must combine the results into a point estimate, a range of values, or a probability distribution for use in their analyses. As discussed later in this article, these decisions are influenced by current government-wide guidance and constrained by the available empirical research.

Perhaps the most important and controversial challenge is determining how to address differences between the types of risks studied and the types of risks addressed by federal regulations. For example, compensating wage studies address the risk of accidental deaths among workers who are, on average, in their mid- to late thirties. However, the individuals affected by air pollution regulations are likely to be much older, may face higher baseline risks from conditions unrelated to pollution, and may experience several years of morbidity (e.g., from heart disease or cancer) prior to death. In addition, exposure to pollution may be less voluntary and controllable than the choice of a job.

The Value of a Statistical Life Year

The value per statistical life year (VSLY) is an approach for adjusting VSL estimates to reflect differences in remaining life expectancy and involves calculating the value of each year of life extension. Because the degree of life extension is usually closely related to the age of the affected individuals, VSLY is often interpreted as an approach for adjusting VSL to reflect age differences. It is generally derived by applying simple assumptions to VSL estimates based on Moore and Viscusi (1988).

More specifically, the VSLY is derived by dividing the VSL by the discounted expected number of life-years remaining for the average individual studied. This approach assumes

that the VSL is the sum of the present value of each life-year (the VSLY) weighted by the probability that an individual survives to that year, which is equivalent to assuming that the value of each remaining life-year is constant. The resulting VSLY is then applied to the expected number of discounted life years saved by the regulation (i.e., to the predicted increase in discounted life expectancy).

An example of this approach appears as a sensitivity analysis in the EPA's retrospective assessment of the Clean Air Act (EPA 1997). Assuming that the VSL is \$4.8 million (in 1990 dollars), the remaining life expectancy averages thirty-five years for the population studied, and the VSL estimate reflects a 5-percent discount rate, the EPA obtained a VSLY of \$293,000. If the average individual whose life is extended by the program would survive for an additional fourteen years (as a result of reduced exposure to pollutants), the present value of the risk reductions would be \$2.9 million (i.e., the discounted value of fourteen years × \$293,000 per year). In other words, under this approach, the total value of the mortality risk reduction would be \$4.8 million for a younger individual who would survive for thirty-five additional years, and \$2.9 million for an older individual who would survive for only fourteen more years.

These VSLY calculations, although easy to implement, assume that the VSL is proportional to the discounted remaining life expectancy. As discussed elsewhere in this volume, economic theory places no such restrictions on the VSL, and the available empirical evidence indicates that the relationship between VSL and life expectancy, or age, is more complex. In addition, because it suggests that saving the life of an elderly individual is worth less than saving the life of a younger individual (who has more remaining life years), such adjustments have been contentious when applied in a public policy setting.

Government-wide Guidance

The US Office of Management and Budget (OMB) has primary responsibility for coordinating and reviewing regulatory analyses across federal agencies. The OMB's role is framed by Executive Order 12866, Regulatory Planning and Review (1993). This executive order directs agencies to evaluate alternative strategies for all economically significant regulations, which include those with a predicted annual impact on the economy of \$100 million or more or with other types of significant effects. The executive order requires the analysis of benefits and costs but its concerns go beyond economic efficiency. It requires agencies to consider distributive impacts and equity as well as nonquantifiable effects.

Current OMB Guidance

Guidance on implementing Executive Order 12866 is provided in the OMB's Circular A-4, Regulatory Analysis (2003). The Circular is intended to assist analysts in conducting good

¹Formally, the approach assumes that the VSL at age j is, $VSL_j = \sum_{t=j}^T q_{j,t} (1+\delta)^{j-t} VSLY$, where $q_{j,t}$ is the probability that an individual at age j survives to age t and δ is the discount rate. VSLY can be factored out of this expression, and $\sum_{t=j}^T q_{j,t} (1+\delta)^{j-t}$ is the discounted remaining life expectancy.

286 L. A. Robinson

regulatory assessments and to promote consistency across agencies. While the OMB treats some of the guidance as mandatory, it also recognizes that agencies may lack the data and resources necessary to fully comply with many of the recommendations. Thus the OMB suggests preferred practices, yet allows agencies to exercise some discretion in determining how to conduct their analyses as long as sufficient justification is provided for the approach. Ultimately, each individual regulatory analysis is the result of negotiations between the OMB and the agency during the OMB review process.

Circular A-4 discusses a wide range of issues, such as identifying alternative policy strategies, assessing various types of costs and benefits, and analyzing distributional impacts. It includes sections that directly address benefits valuation (briefly summarized below), as well as related topics such as selecting a discount rate and assessing uncertainty.

The Circular describes principles that agencies should consider in reviewing the research used to support benefit valuation. For example, it provides lists of criteria for evaluating revealed and stated preference studies as well as for transferring benefit estimates from the studies to different policy contexts. These criteria address whether the study is consistent with economic theory, uses appropriate methods for data collection and analysis, and considers outcomes similar to those anticipated from the proposed rulemaking. Separately, the OMB has issued guidance on quality control and peer review (OMB 2002, 2004), which (in combination with Circular A-4) increases the emphasis on assessing the quality and suitability of studies used for valuation. The OMB notes, however, that ultimately the selection of appropriate values will depend on the professional judgment of the analyst because each study is likely to have both strengths and weaknesses. Circular A-4 repeatedly emphasizes the need to discuss the rationale for selecting a particular approach and to assess associated biases or uncertainties.

In the Circular, the OMB also discusses the valuation of mortality risk reductions and suggests that agencies present both VSL and VSLY estimates. The OMB notes that these values are subject to continued research and debate and indicates that agencies should describe the limitations of their chosen approach. The Circular reports that the range of VSL estimates found in the literature is generally between \$1 million and \$10 million; as a result, regulatory agencies generally use values from within this range.

In addition, Circular A-4 discusses options for adjusting VSL estimates to reflect differences between the scenarios addressed in the research literature and the specific regulatory scenarios being assessed. The Circular notes that the available empirical research supports quantitative adjustments to VSL estimates only for changes in income over time and for time lags in the incidence of health impacts. It includes cautions on the application of age adjustments and suggests the use of larger VSLY estimates for older individuals. It also requires that agencies complete a cost-effectiveness analysis as well as a benefit-cost analysis. In cost-effectiveness analysis, regulatory costs are divided by a nonmonetary benefit measure (such as lives or life-years saved) to compute the cost per unit of effect (e.g., the cost per life-year saved), whereas benefit-cost analysis assigns a monetary value to each type of benefit.

The "Senior Discount" Debate

While the OMB was developing *Circular A-4*, a controversy erupted over the "senior discount" implicit in age-adjusted VSL estimates used by the EPA. The EPA's preferred VSL estimates do not vary by age. However, for many air pollution rules, most of the reduction in premature mortality is likely to accrue to individuals aged sixty-five and over rather than to the younger working-age individuals included in most VSL studies. In some of its regulatory assessments, the EPA presented sensitivity analyses based on research suggesting that older individuals are willing to pay less for life-saving interventions than younger adults (e.g., Jones-Lee 1989; Jones-Lee et al. 1993). Many observers objected to this use of lower VSL estimates for older persons in policy analysis. The controversy garnered attention from the media and Congress; advocacy groups ran ads showing "seniors on sale" and, in the fiscal year 2004 Appropriations Bill (H.R. 2673), Congress prohibited the EPA from funding analyses that made these adjustments.

In response, the OMB issued a memorandum advising agencies against adjusting the VSL for age (Graham 2003). This memorandum suggested that more recent research (ultimately published in Alberini et al. 2004a) did not fully support the VSL age adjustment found in earlier studies. It indicated that, when VSLY estimates are used instead of VSL, the yearly values are likely to be higher for senior citizens because "seniors face larger overall health risks from all causes and because they have accumulated savings and liquid assets to expend on protection of their health and safety" (Graham 2003, p. 2). The memorandum also noted that the OMB was developing requirements for cost-effectiveness analysis, which has the advantage of not requiring that a monetary value be placed on risk reductions (although such values are implicit in the ultimate regulatory decision).

However, the guidance in this OMB memorandum, which was eventually incorporated into *Circular A-4*, does not necessarily eliminate the use of different values for younger versus older individuals. When VSLY estimates are applied, the total value of a risk reduction is equal to the product of the VSLY estimate and the discounted number of life-years saved. Unless the VSLY estimates for older individuals are large enough to compensate for the smaller number of life-years remaining, the use of VSLY estimates will result in lower values for older individuals. In addition, the measures most commonly used to value premature mortality in cost-effectiveness analyses are based on life-years lost (see Institute of Medicine 2006) and thus also result in smaller values for older persons.

The number of rules subject to these OMB requirements is small but their economic impact is substantial. For example, in fiscal year 2004, the OMB reviewed only six final rules that were economically significant, included monetized estimates of health or safety benefits, and were subject to Executive Order 12866 (OMB 2005). However, the OMB calculated that the annual costs of these rules totaled approximately \$3.5 billion and their monetized benefits totaled between \$12 billion and \$107 billion (2001 dollars). Of these six rules, three were the EPA air pollution rules for which reduced mortality risks accounted for a significant fraction (roughly 90 percent) of total monetized benefits. Data for other years show a similar pattern; the EPA air pollution rules account for a significant proportion of all economically significant health and safety regulations and their monetized benefits are attributable primarily to reductions in premature mortality.

288 L. A. Robinson

The EPA's Approach

The EPA has devoted considerable attention to developing methods for estimating the value of reductions in the risks of premature mortality. While the studies that are used as the basis for these estimates have remained relatively constant over time, the EPA's approach to adjusting the estimates has evolved as the result of continuing research and expert review.

The EPA's Base Estimates

The EPA's VSL estimates are based largely on work completed in the early 1990s to support its retrospective and prospective analyses of the impacts of the Clean Air Act (EPA 1997, 1999a; summarized in more detail in Industrial Economics, Incorporated [IEc] 2001). Reflecting research conducted by Viscusi (1992, 1993), the EPA identified twenty-six VSL estimates suitable for use in its analyses, of which twenty-one were from wage-risk studies and five were from contingent valuation studies.

The mean VSL estimates from these studies ranged from \$0.6 million to \$13.5 million with an overall mean of \$4.8 million (1990 dollars). When updated to 2005 dollars using the Consumer Price Index, the mean of this range is \$7.2 million, with a minimum of \$0.9 million and a maximum of \$20.2 million. The wage-risk studies provide values scattered throughout this range, but the estimates from the contingent valuation studies tend to cluster towards the lower end (see Appendix Table A1).

These estimates rely primarily, but not entirely, on studies of US workers, and focus on accidental deaths. The workers studied are, on average, in their mid- to late-thirties and their average income varies from close to \$10,000 to over \$40,000 (in 1990 dollars), reflecting the differing populations and job categories addressed by each study. Almost all of the studies address job-related risks. The magnitude of the risks average from about one in one hundred thousand to about seven in ten thousand annually, and tend to cluster around one in ten thousand.

The studies vary in other ways (e.g., sample sizes used, characteristics of the underlying data, extent to which they adjust for potentially significant variables such as the availability of workers' compensation) that may affect both their quality and their suitability for use in environmental policy analysis. They also were designed to address a variety of different concerns, such as investigating the effects of gender, unionization, job type, location, and/or risk perceptions on VSL estimates. The nature of these concerns, in turn, affected the data incorporated into the study design and the variables used in the statistical analysis.

The approach developed for the Clean Air Act analysis, based on these twenty-six VSL estimates, was ultimately incorporated into the EPA's *Guidelines for Preparing Economic Analysis* (EPA 2000a). For many years, the central tendency (or mean) VSL estimate used in EPA regulatory analyses was derived from this range of values, adjusted as needed for inflation.

Recently, researchers have completed several analyses that use statistical methods to combine data from various VSL studies (often called "meta-analyses"). These studies include Mrozek and Taylor (2002), Kochi et al. (2006), and Viscusi and Aldy (2003), each of which uses a somewhat different methodology and reports different ranges of best estimates. For example, Mrozek and Taylor (2002) report a mean VSL of \$2.6 million (1998 dollars)

for the average worker, Kochi et al. (2006) report a mean of \$5.4 million (2000 dollars) with a standard deviation of \$2.4 million, and Viscusi and Aldy (2003) report means ranging from \$5.5 million to \$7.6 million (2000 dollars) depending on the model specification used.

The EPA has begun to use these meta-analysis results when assessing the impacts of its air pollution rules (e.g., EPA 2004, 2005a) while continuing to rely on the twenty-six studies for other rules, such as those addressing drinking water (e.g., EPA 2005b). When applying the meta-analysis results, the EPA uses a range of estimates, anchored at \$1 million (near the lower end of the range from Mrozek and Taylor) and \$10 million (near the upper end of the range from Viscusi and Aldy), with a mean of \$5.5 million (1999 dollars).

This approach results, in part, from the advice of a special panel of the EPA's Science Advisory Board (Cameron et al. 2004). In its review of the plans for the EPA's Second Prospective Analysis of the Clean Air Act, this panel suggested that the agency focus primarily on the results of Viscusi and Aldy (2003) meta-analysis and also incorporate lessons learned from the other studies. This approach is also consistent with the range reported in the OMB's Circular A-4 discussion of values to be used in regulatory analysis.

Over time, various aspects of the EPA's approach have been reviewed by independent committees of its Science Advisory Board (e.g., Cropper 2001; Schmalensee 1993; Stavins 1999, 2000), and have been subject to extensive public comment. Most of these reviews suggested that additional research is needed to refine the base VSL estimates, but did not provide a specific alternative that could be applied in the near term. In addition, many of the reviews discussed the differences between the scenarios studied and the scenarios addressed by the EPA regulations, as described below.

The EPA's Adjustments for Scenario Differences

Throughout the development of the EPA's VSL estimates, the agency and its advisory panels have struggled with issues related to the differences among the scenarios being assessed. The populations and risks affected by the EPA's regulations differ in several important ways from those addressed by the studies (EPA 2000b; IEc 2001). As noted earlier, the twenty-six studies focus largely on the risks of accidents affecting middle-aged workers. In contrast, the EPA's policies affect premature mortality from illnesses that may be spread more widely throughout the population or concentrated in younger or older age groups. The populations may differ not only in their age, but also in their income, health status, and/or degree of risk aversion. The types of health risks may differ in their timing or duration, in their voluntariness or controllability, and in the extent to which they are dreaded. For example, air pollution controls will not immediately reverse all the effects of a lifetime of exposure, and many pollution-related illnesses (such as cancers) may be particularly dreaded because they include a period of morbidity prior to death.

Because only limited data are available on the effects of these varying scenarios, it is not possible to modify the VSL estimates from the research literature to reflect most of these differences. The EPA has adjusted its base estimates for income growth and for any delays in the incidence of risk reductions (often referred to as cessation lags) in most regulatory analyses; adjustments for other factors (in either the base case or sensitivity analysis) have

290 L. A. Robinson

been made in only a few cases. The effects of these other factors are instead described qualitatively.

This approach is consistent with the advice of several EPA advisory panels. For example, two Science Advisory Board groups (Cropper 2001; Stavins 2000) did not support an adjustment for voluntariness and controllability included in sensitivity analysis of the benefits of the EPA's rule governing arsenic in drinking water. More generally, the Science Advisory Board's Environmental Economics Advisory Committee (Stavins 2000) suggested that the available evidence supported quantitative adjustments only for income growth and cessation lag when valuing cancer-related fatalities.

With regard to age adjustments, the position of the EPA's advisory panels has changed over time. In response to the concerns about the equitable treatment of younger and older individuals, the EPA has discontinued its use of VSLY estimates as well as VSL age adjustments in recent analyses. The following sections discuss in more detail the issues related to VSL adjustments for age, income, and time lags.

Age Adjustments

As noted in the earlier discussion of the senior discount debate and its effect on the OMB's guidance, age adjustments have been a particularly contentious issue. While the average age of the population included in the VSL studies is in the mid- to late-thirties, some EPA regulations have disproportionate effects on different age groups. Most significantly, for air rules addressing particulate matter, roughly 80 percent of the reduction in premature mortality may occur among individuals over age sixty-five (EPA 1999a).

As the result of its own research and negotiations with the OMB during the regulatory review process, the EPA included sensitivity analyses of the effects of age adjustments (adjusting VSL and/or applying VSLY estimates) in several of its reports prior to the development of *Circular A-4*. The Tier 2 rule governing air emissions from motor vehicles (EPA 1999b) is one example of a regulatory analysis that includes age adjustments in sensitivity analysis.³

While certain of the older EPA analyses report VSLY estimates, research suggests that such calculations are overly simplistic. In particular, some studies have indicated that there is an inverse U shaped relationship between age and the VSL, which peaks in middle age (e.g., Jones-Lee 1989; Jones-Lee et al. 1993). Another study (Alberini et al. 2004a) found that US respondents over age seventy were willing to pay about 20 percent less than individuals aged forty to seventy to reduce their risk of premature mortality; however, this result was not statistically significant.

The EPA has used these studies to adjust VSL estimates in illustrative analyses. For example, for the heavy-duty diesel rule (EPA 2000c), the EPA used VSL age adjustments

²One Science Advisory Board group (Cropper 2001) recommended adding medical treatment costs to VSL estimates to reflect the impacts of morbidity prior to death; however, this adjustment has been rarely applied.

³Several other EPA policy analyses (not technically subject to *Circular A-4* because they are not regulatory proposals) also include these adjustments in sensitivity analysis, such as the retrospective assessment of the Clean Air Act (EPA 1997), the prospective assessment of the Clean Air Act (EPA 1999a), and the Clear Skies legislative proposals (EPA 2003b).

based on Jones-Lee (1989) and Jones-Lee et al. (1993) in sensitivity analysis, which reduced its primary benefits estimate by 10 or 40 percent, depending on the adjustment factor applied. In a sensitivity analysis for regulations addressing emissions from large spark ignition engines (EPA 2002), the agency used a more complicated approach that reflected initial results from the work of Alberini et al. (2004a) as well as the adjustment factor from Jones-Lee (1989). In this case, the EPA combined the age adjustments with a lower base VSL (\$3.7 million instead of \$6.1 million) that included only the five contingent valuation studies (see Appendix Table A1). As a result, the age-adjusted values for both younger and older individuals were substantially lower than the base estimates for all age groups.

As discussed above, because these and other approaches to age adjustments have raised serious concerns about the equitable treatment of younger and older individuals in policy decisions, the EPA has not used VSLY estimates or VSL age adjustments in its more recent analyses. This evolution of the EPA's practices is consistent with the advice of its advisory panels. For example, a 1993 review of the EPA's approach to the retrospective analysis of the Clean Air Act suggested that the VSL should be adjusted to reflect the number of life years saved (Schmalensee 1993). A similar suggestion was contained in a 1999 review of the EPA's guidelines for economic analysis, which recommended that age adjustments be included in sensitivity analysis (Stavins 1999). However, a subsequent panel reviewing the valuation of cancer-related fatalities indicated that, rather than relying on simple VSLY calculations, "the theoretically appropriate method is to calculate WTP for individuals whose ages correspond to those of the affected population" and "urges that more research also be conducted on this topic" rather than recommending the implementation of adjustments based on currently available studies (Stavins 2000, p. 8). The Environmental Economics Advisory Committee of the EPA's Science Advisory Board is now revisiting this issue, and is expected to recommend against the use of VSLY estimates.

Valuing risks to children raises additional concerns. For example, measuring a child's own WTP for his or her health risk reductions is problematic—it is more feasible to measure adult WTP for reducing risks to children. However, parents' values for their children may be higher than their WTP to reduce their own risks and may differ from societal values (see EPA 2003a). Because of the lack of relevant research, the EPA and other agencies generally use the same values for both adults and children. The OMB's *Circular A-4* indicates that the values for children should be at least as large as the values used for adults.

Income Adjustments

Income has a clear and measurable effect on the VSL: as income increases, WTP for risk reductions usually increases. While this effect could be measured both cross-sectionally (across individuals or subpopulations) and longitudinally (over time), most studies are cross-sectional. However, using different VSL estimates for individuals with different incomes is controversial and has raised issues about the equitable treatment of richer and poorer segments of the population in policy decisions. Thus the EPA does not make cross-sectional adjustments in its analyses.

Instead, the EPA uses the cross-sectional data to estimate the longitudinal change in VSL likely to occur as real per capita income (measured by gross domestic product [GDP]) changes over time. This adjustment involves estimating the percentage change in the VSL

L. A. Robinson

that is associated with a 1 percent change in income (i.e., its income elasticity). Because most studies suggest that this elasticity is less than one, several EPA analyses have used a distribution of income elasticity estimates with a mode of 0.40 and endpoints at 0.08 and 1.00 (EPA 1999a). The EPA typically first adjusts the VSL estimates to a common base year (often 1990), and then applies the adjustment for real income growth over the future time period considered in the analysis. The same estimates of income-adjusted VSL are then used for all members of the population affected by the rulemaking.

Time Lag Adjustments

Another difference between the accidental deaths addressed by most VSL studies and the impacts of some environmental contaminants is the possibility of a time lag between changes in exposure and changes in premature mortality. This lag is often referred to as "latency" when the results of exposure are not immediately manifest. However, in its analyses, the EPA is usually concerned instead with the "cessation lag," which refers to the delay between decreased exposure and achievement of the full reduction in health risks.

The most extensive research on cessation lag relevant to the EPA's regulations addresses cigarette smoking, and suggests that the duration of this lag may differ significantly from the latency period. For example, an expert panel that reviewed the EPA's rule for arsenic levels in drinking water noted that smoking studies suggest that "the latency between initiation of exposure and an increase in lung cancer risk is approximately 20 years. However, after cessation of exposure, risk for lung cancer begins to decline rather quickly" (Cropper 2001, p. 5). The EPA's subsequent analysis (reported in EPA 2005b) suggested that 80 percent of the lung cancer benefits were likely to accrue prior to twenty years after cessation of exposure.

Until recently, there was little research that directly addressed the effects of such lags on VSL estimates. Thus, for many years, the EPA used simple discounting to account for this effect. For example, if the pollution reduction occurred in the current year but a portion of the risk reduction occurred five years later, then the VSL would be discounted to reflect the five-year delay, using the same discount rate as applied elsewhere in the analysis.⁴ Recent studies would appear to support the use of discounted values for delayed impacts (e.g., Alberini et al. 2004b; Hammitt and Liu 2004), although the estimates of the extent of the discount vary.

The EPA is now revising its Guidelines for Preparing Economic Analysis (2000a), as well as updating its approach for its next prospective analysis of the Clean Air Act, and has asked the Environmental Economics Advisory Committee of its Science Advisory Board to further assess these issues. To support this effort, the EPA completed a review of the VSL literature (Dockins et al. 2004) that summarized recent studies and meta-analyses. The EPA also funded research on the robustness of estimates from wage-risk and contingent valuation studies (Alberini 2004; Black, Galdo, and Lin 2003), as well as from studies of averting behavior (i.e., measures that individuals undertake to avoid or mitigate risks, such as the use of seat belts) (Blomquist 2004). The EPA subsequently convened a group of statisticians to

⁴Circular A-4 generally requires that agencies report the results using two alternate discount rates (3 and 7 percent) and also report the undiscounted values over time.

address the use of meta-analysis (EPA 2006) and conducted a review of the literature on the relationship between life expectancy and the VSL (Dockins et al. 2006). The committee's review is ongoing, and its final report on the use of meta-analysis and adjustments for life expectancy is expected sometime in 2007.

Approaches Used by Other Agencies

Other agencies promulgate fewer economically significant rules that require valuing the risk of premature mortality. Between October 2003 and September 2005, four agencies (in addition to the EPA) prepared final rules with quantified health and safety benefits that were reviewed by the ÓMB (OMB 2005, 2006). These agencies included the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) in the Department of Health and Human Services (HHS), as well as the National Highway Traffic Safety Administration (NHTSA) and the Federal Motor Carrier Safety Administration (FMCSA) in the Department of Transportation (DOT). An earlier review, covering the period between January 2000 and June 2004, reported similar patterns in agency promulgation of major health and safety rules (Robinson 2004).

The HHS Agencies (the FDA and the CMS)

The FDA does not provide formal internal guidance for economic analysis, but it applies a similar approach across many of its rules. For premature mortality, the agency often uses a VSL estimate of \$5 million, without specifying a dollar year, and occasionally provides alternative estimates using higher or lower values (see, e.g., FDA 2003, 2004, 2005). This estimate is roughly in the middle of the \$1 million to \$10 million range cited in *Circular A-4* (OMB 2003).

The FDA rarely adjusts its VSL estimates for scenario differences, although it has addressed cessation lag (e.g., in its trans-fat rule, FDA 2003), and added the cost of cancer treatment (\$25,000) and an adjustment for psychological factors (\$5,000) to the VSL for a rule on X-rays (FDA 2005). Thus, while its base VSL estimates are similar to those used by the EPA, the values ultimately applied by the FDA may be quite different because of the income growth and other adjustments made by the EPA. A few FDA analyses have presented alternative estimates of the value of mortality risk reductions using VSLY as well as VSL estimates (e.g., FDA 2003).

However, VSLY estimates are a key component of the FDA's approach for valuing nonfatal risk reductions. The FDA first assesses the quality-adjusted life year (QALY) gains associated with reducing the risk of each nonfatal health condition, and then uses VSLY estimates to value each QALY. The FDA next adds medical costs to these monetized QALYs to determine the total benefits per statistical case of illness averted (see Institute of Medicine 2006 for more information). The FDA follows this process primarily because of the scarcity of WTP estimates for the health effects of concern.

In recent analyses (e.g., FDA 2003, 2004, 2005), the FDA has applied VSLY values ranging from about \$100,000 to \$500,000 per life-year. The low end of this range is based on estimates occasionally used in the health economics literature (see FDA 2003), while the higher values are derived from its VSL estimates using the same simple VSLY approach as described earlier.

294 L. A. Robinson

Another HHS agency, the CMS, develops few economically significant rules with health and safety impacts; most of its programs involve transfers (e.g., from taxpayers to Medicare and Medicaid recipients) and hence are not subject to the OMB requirements for regulatory analysis. In its immunization rule (CMS 2005), the CMS applies the same VSL estimate as the FDA (\$5 million), noting that it is roughly the mid-point of the range of values suggested by the OMB.

The DOT Agencies (the NHTSA and the FMSCA)

Both the NHTSA and the FMCSA rely on the DOT-wide guidance for their base VSL estimates. The DOT currently recommends the use of a \$3.0 million VSL—noting that this value is imprecise and should be used as "a guide for thoughtful decision-making" (DOT 2002, p. 1). Its approach is based largely on the results of Miller (1990), with adjustments for inflation and newer studies. Miller's 1990 estimates vary from those used by the EPA because he applies different criteria to determine which studies to include, and adjusts the results to address certain limitations of the studies. The DOT indicates that it continues to review the literature and consider whether changes to this value are needed (DOT 2002).

In contrast to the EPA and the HHS agencies, these DOT agencies primarily address injury-related accidental deaths rather than deaths from illness. Hence, the scenarios they assess are in some respects more similar to the scenarios addressed by available VSL studies. The DOT agencies do not, however, adjust their values for relevant scenario differences (such as changes in real income over time) but instead add on certain costs that may not be reflected in the VSL estimates.

Both the NHTSA and the FMCSA adjust the DOT's base VSL estimate to reflect lost productivity and various types of expenditures, although the details of the adjustments vary slightly. Under the assumption that the VSL estimates include the expected loss of after-tax wages and household production (i.e., unpaid work in the home), the agencies first subtract estimates of these productivity losses from the base VSL estimate. They then add updated estimates of crash-related losses in market and household productivity as well as other expenditures, such as those related to medical treatment, emergency services, insurance administration, workplace disruption, and litigation (NHTSA 2002, Zaloshnja and Miller 2002). After these adjustments, the per victim value for fatal injuries becomes approximately \$2.7 million to \$3.3 million (depending on the type of crash) excluding property damage (2000 dollars). Each agency recalculates these adjusted estimates periodically and applies the results across subsequent analyses (see, e.g., FMCSA 2005, NHTSA 2005). In recent assessments, these agencies also include sensitivity analyses using higher values.

Similar to the FDA, these DOT agencies use VSLY estimates to determine the monetary value of QALY gains when addressing nonfatal (rather than fatal) risk reductions. However, the details of their approaches differ substantially, as described in Robinson (2004).

Summary and Conclusions

Current OMB guidance suggests that VSL estimates range from about \$1 million to \$10 million. Review of agency practices suggests that they generally use values that fall within this range. For example, the central tendency of the range of twenty-six estimates used in

many EPA analyses is \$7.2 million (2005 dollars), while the mean EPA estimate based on recent meta-analyses is \$5.5 million (1999 dollars). The FDA generally uses an estimate near the middle of the range (\$5 million, no dollar year reported), while the DOT has consistently applied a lower value (\$3 million in recent guidance).

The EPA adjusts its base VSL estimates to reflect income growth over time and any time lags between the reduction in exposure and the reduction in incidence. In contrast, the FDA adjusts for these differences infrequently. The DOT agencies do not make these adjustments, but add other expenditures to VSL estimates. Adjustments for age have been a particularly contentious area, and the EPA has discontinued the practice of including these adjustments in sensitivity analyses in response to concerns about the equitable treatment of younger and older individuals in policy analysis.

This review leads to several conclusions. First, the value of reducing premature mortality risks has been relatively well studied. In contrast, analysis of the costs and benefits of major regulations requires that agencies address a number of other complex and difficult issues for which data may be more limited. For example, agencies may need to assess the risks to human health associated with contaminants whose effects are only partially understood, or determine the costs of industry compliance despite limited ability to foresee technological innovations. In comparison, the number of VSL studies is large and provides useful information on the possible range of values. However, more research is needed to address the specific scenarios reflected in federal regulations.

Second, experience with the debate over age adjustments suggests that it is difficult for agencies to ignore equity issues when valuing mortality risks. Economists often argue that benefit-cost analysis is best suited for assessing economic efficiency, and that it is preferable to address concerns related to equity and the distribution of impacts separately. While studies of individual WTP indicate that the VSL varies with age and income, using different VSL estimates for different segments of the population has led some observers to question the fairness of policy deliberations. As a result, federal agencies generally apply the same mean VSL estimates across all individuals potentially affected by their regulations—regardless of age, income, or other characteristics.

Third, the use of different VSL estimates across agencies could lead to different levels of investment in life-saving regulations if the quantified estimates of benefits and costs were the only factors considered by policy-makers. For example, if two agencies were each considering a regulation with identical costs and mortality risk impacts, the agency using the lower VSL estimate might select a less costly option. In theory, the risks addressed by different agencies could have different monetary values due to variation in the nature of the risks and the populations affected. In reality, the differences across agencies appear instead to reflect variation in their approaches to addressing limitations in the available VSL research.

Finally, it is difficult to determine how the choice of a VSL estimate influences regulatory decisions, in part because many decisions are made at the same time that the analysis is undergoing review and revision. Although regulatory decisions are rarely based solely on the results of economic analyses, the variation in values argues for careful assessment and presentation of the uncertainty in the VSL estimates used throughout the regulatory development process.

Appendix Table A1 Selected characteristics of VSL studies used by the EPA (1990 dollars)

Study	Mean VSL estimate	Population studied	Valuation method	Average age of sample	Average income of sample	Type of risk	Mean risk
Kniesner and Leeth (1991)	\$0.6 million	US manufacturing workers	Wage-risk	37 years	\$26,226	Job-related	40/100,000
Smith and Gilbert (1984), based on Smith (1983)	\$0.7 million	US metropolitan area workers	Wage-risk	NR	NR	Job-related	NR
Dillingham (1985)	\$0.9 million	US workers	Wage-risk	36 years	\$20,848	Job-related	10/100,000
Butler (1983)	\$1.1 million	S. Carolina workers	Wage-risk	NR	NR	Job-related	5/100,000
Miller and Guria (1991)	\$1.2 million	New Zealand residents	Contingent valuation	NR	NR	Road safety	NR
Moore and Viscusi (1988)	\$2.5 million	US workers	Wage-risk	37 years	\$19,444	Job-related	5/100,000
Viscusi, Magat, and Huber (1991)	\$2.7 million	US residents	Contingent valuation	33 years	\$43,771	Auto accidents	1/100,000
Marin and Psacharopoulos (1982)	\$2.8 million	UK workers	Wage-risk	ŃR	\$11,287	Job-related	10/100,000
Gegax, Gerking, and Schulze (1991)	\$3.3 million	US workers	Contingent valuation	NR	NR	Job-related	70/100,000
Kneisner and Leeth (1991)	\$3.3 million	Australian manufacturing workers	Wage-risk	NR	\$18,177	Job-related	10/100,000
Gerking, de Haan, and Schulze (1988)	\$3.4 million	US workers	Contingent valuation	· NR	NR	Job-related	NR
Cousineau, Lacroix, and Girard (1992)	\$3.6 million	Canadian workers	Wage-risk	, NR	NR	Job-related	1/100,000
Jones-Lee (1989)	\$3.8 million	UK residents	Contingent valuation	NR	NR	Auto accidents	NR
Dillingham (1985)	\$3.9 million	US workers	Wage-risk	36 years	\$20,848	ob-related	8/100,000
Viscusi (1978, 1979)	\$4.1 million	US workers	Wage-risk	40 years	\$24,834	ob-related	10/100,000
Smith (1976)	\$4.6 million	US workers	Wage-risk	ŃR	NR	Job-related	10/100,000
Smith (1983)	\$4.7 million	US workers	Wage-risk	NR	NR	Job-related	NR
Olson (1981)	\$5.2 million	US workers	Wage-risk	37 years	NR	Job-related	10/100,000
Viscusi (1981)	\$6.5 million	US workers	Wage-risk	NR	\$17,640	Job-related	10/100,000
Smith (1974)	\$7.2 million	US workers	Wage-risk	NR	\$22,640	Job-related	NR
Moore and Viscusi (1988)	\$7.3 million	US workers	Wage-risk	37 years	\$19,444	Job-related	8/100,000
Kniesner and Leeth (1991)	\$7.6 million	Japanese manufacturing workers	Wage-risk	ŃR	\$34,989	Job-related	3/100,000
Herzog and Schlottmann (1990)	\$9.1 million	US manufacturing workers	Wage-risk	NR	NR	Job-related	NR
Leigh and Folson (1984)	\$9.7 million	US workers	Wage-risk	NR	\$27,693	Job-related	10/100,000
Leigh (1987)	\$10.4 million	US workers	Wage-risk	NR	NR	Job-related	NR
Garen (1988)	\$13.5 million	US workers	Wage-risk	NR	NR	Job-related	NR

Sources: Derived from EPA (1997), table I-1, and Industrial Economics Incorporated (2001), exhibit 4-2. Average income and risk level are based on Viscusi (1993), tables 2 and 6, and additional review of the individual studies.

Notes: 1990 dollars. "NR" indicates "not reported;" however, many of these studies are based on data sources that are similar to those for which these variables are reported.

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298 L. A. Robinson

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